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The clinical effectiveness of CBT-based guided self-help for anxiety and depression: Does it work in practice and what helps people to benefit?

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Firstly, I wish to thank all those individuals whose valuable participation made this study possible. I hope that in some small way the findings from this study will help inform guided self-help services to optimise future patients' experience. Thank you.

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WORD COUNT: 26,830

ABSTRACT

Objectives. To examine the clinical effectiveness of guided self-help (GSH) for anxiety and depression in routine clinical practice, and the role of self-efficacy, therapeutic alliance and socio-economic status in influencing that effectiveness.

Design. A within-subjects repeated measures design in which participants served as their own controls by completing questionnaires across a control period prior to GSH intervention, then again at post-intervention and 3- and 6-month follow-up.

Methods. GSH participants completed outcome measures for mental health (HADS) and work/social functioning (WSAS). Factors explored by regression as possible predictors of effectiveness were self-efficacy, therapeutic alliance and socio-economic status.

Results. Sixty people completed GSH, with analyses indicating effectiveness of GSH in significantly improving mental health and social functioning at post-treatment and 3-month follow-up, but not at 6-month follow-up. Effectiveness was also indicated under intent-to-treat conditions (n = 97) with medium effect sizes (≈ 0.6) for each outcome measure at post-treatment. Improvement in mental health was predicted by lower self-efficacy and greater therapeutic alliance. Completers of the intervention had significantly higher socio-economic status than non-completers.

Conclusions. The current study has suggested effectiveness of GSH in routine clinical practice across different primary care services at post-treatment, but with less evidence of this at follow-up. Effectiveness has been highlighted to be influenced by self-efficacy and therapeutic alliance, suggesting the importance of considering non-specific factors when patients access GSH in primary care. This study underlines the need for further research exploring longer-term clinical effectiveness and examining for whom GSH works in order to constructively inform future evidence-based practice.

Word count: 252

1. SYSTEMATIC REVIEW

Title

The clinical effectiveness of CBT-based guided self-help interventions for anxiety and depressive disorders: A systematic review

Abbreviated Title for Running Head

Review of guided self-help for anxiety and depression

Abstract*

Background. CBT-based guided self-help (GSH) has been suggested to be an effective intervention for mild to moderate anxiety and depression, yet the evidence seems inconclusive, with some studies reporting that GSH is effective and others finding that GSH is ineffective. Guided self-help differs in important respects from other levels of self-help, yet the literature regarding exclusively *guided* self-help interventions for anxiety and depression has not been systematically reviewed.

Method. A literature search for randomised controlled trials examining CBT-based guided self-help interventions for anxiety and depressive disorders was conducted. Multiple electronic databases were searched; several journals spanning key disciplines were hand-searched; reference lists of included review articles were scanned and relevant first authors were contacted.

Results. Thirteen studies met the inclusion criteria. Meta-analysis indicated effectiveness of GSH at post-treatment, though GSH was found to have limited effectiveness at follow-up or amongst more clinically representative samples. Studies which reported greater effectiveness of GSH tended to be of lower methodological quality and generally involved participants who were self-selected rather than recruited via clinical referrals.

Conclusions. While there is support for the effectiveness of CBT-based guided self-help amongst media-recruited individuals, the finding that the reviewed RCTs had limited

* As Chapter 1 is published within *Psychological Medicine* (Coull & Morris, 2011) it is formatted according to the author guidelines for that journal (see Appendix 1)

effectiveness within routine clinical practice suggests that the current evidence is inconclusive. Further rigorous evidence based on clinical populations which examines longer-term outcomes is required before CBT-based GSH interventions can be deemed effective for adults accessing primary care services for treatment of anxiety and depression.

Abstract word count: 240

Key words: CBT, clinical practice, effectiveness, review, self-help.

Introduction

There has been a recent impetus in the UK to improve patients' access to psychological therapies (Department of Health, 2005). This has been targeted through a stepped care model in which the intensity of intervention is matched to the severity of mental health symptoms. Stepped care has the potential to maximise clinical benefits from available therapeutic resources (Bower & Gilbody, 2005). National Institute for Clinical Excellence (NICE) guidelines recommend the provision of cognitive-behavioural therapy (CBT) based guided self-help (GSH) intervention for anxiety and depressive disorders as part of the stepped care approach (NICE, 2007; 2009). Despite national recommendations advocating guided self-help, the evidence appears inconclusive and a systematic review of exclusively *guided* self-help interventions for anxiety and depressive disorders has not been conducted.

Guided self-help can be regarded as a slightly more intensive treatment than 'pure' self-help, in that it involves the support of a health professional to 'guide' the patient in the use of a self-help intervention or 'health technology' (e.g. a written manual or website). Thus, a key difference between guided self-help and non-guided self-help interventions is the presence of therapist input and the potential impact of therapist factors upon GSH effectiveness outcomes. There is considerable variability within guided self-help interventions in terms of: the experience and type of professional providing the guidance; the quantity of input provided; and the nature of the health technology being advocated. While effectiveness for guided self-help interventions for depression has been indicated in some instances (e.g. Gellatly *et al*. 2007), the evidence

for effectiveness within clinical research trials or routine primary care services varies considerably (Khan *et al*. 2007). For instance, Lucock *et al*. (2008) describe controlled studies of GSH which have not demonstrated clinical benefits and highlight the minimal number of well-designed controlled studies of GSH, whilst Lovell *et al*. (2008) convey the lack of consensus regarding the optimal format and provision of GSH. These conclusions, as well as a tendency within research literature for a blurred demarcation between the concepts of guided self-help and non-guided self-help interventions, indicate the importance in specifically reviewing the clinical effectiveness of *guided* self-help for anxiety and depressive disorders.

Systematic reviews of research examining *self*-help interventions for anxiety and depressive disorders indicate their effectiveness (e.g. Bower *et al*. 2001; Morgan & Jorm, 2008), but temper their conclusions due to the heterogeneous mix of self-help interventions reviewed. Other reviews within the area have either: not been systematic (e.g. Newman *et al*. 2003); not distinguished between 'pure' self-help and guided self-help (e.g. den Boer *et al*. 2004); or have reviewed a combination of both self-help *and* guided self-help interventions (e.g. Gellatly *et al*. 2007). Given: i) the ambiguity surrounding the effectiveness of *guided* self-help interventions (particularly in the longer-term); ii) the inherent differences between GSH and non-guided ('pure') self-help; and iii) the absence of a systematic review *exclusively* examining the effectiveness of *guided* self-help interventions for anxiety and depression, the aim of this review was to systematically evaluate the clinical effectiveness of *guided* self-help interventions for anxiety and depressive disorders.

Method

The authors' reporting within this systematic review followed guidance as outlined by the *Centre for Reviews and Dissemination* (http://www.york.ac.uk/inst/crd/) which forms part of the *National Institute for Health Research* and produces internationally accepted guidelines for undertaking systematic reviews.

Inclusion and exclusion criteria

Study design

Studies were eligible for inclusion if they reported randomised controlled trials (RCTs) which examined guided self-help interventions in comparison to either: 'pure' self-help (i.e. interventions without therapist contact); usual psychological treatment (e.g. standard CBT); or waiting list control conditions.

Population

Included studies were based solely on adult participants (within the age range of 17-64) with anxiety or depressive disorders, regardless of gender, race or nationality. Presence of anxiety or depressive disorder was based upon either structured clinical interview for assessment of a diagnosis according to DSM-IV or ICD-10 criteria, or indicated via validated assessment scales adopting cut-off scores to establish clinically significant symptomatology (i.e. 11+ on the anxiety scale of the Hospital Anxiety and Depression Scale: Zigmond & Snaith, 1983; 3+ on the General Health Questionnaire: Goldberg & Williams, 1988; 16+ on the Center of Epidemiologic Studies – Depression scale: Bouma *et al*. 1995; or 14+ on the Beck Depression Inventory-II: Beck *et al*. 1996). Anxiety disorders included within this review are: panic disorder (with or without agoraphobia);

generalised anxiety disorder; obsessive-compulsive disorder; social anxiety/phobia; phobias; and mixed anxiety disorder samples. Major depressive disorder populations were included in this review, whilst sub-threshold clinical depression and dysthymia were excluded.

Interventions

Definitions of guided self-help vary between studies; Lovell *et al*. (2008) refer to guided self-help as "involving a CBT-based self-help resource and limited support from a healthcare professional", while Mead *et al*. (2005) describe the guided self-help model as an example of minimal contact where the focus is on self-help, but the therapist teaches effective use of the self-help resource. Guided self-help can be provided either by professionals (i.e. therapists with a postgraduate mental health qualification) or provided by para/non-professionals (i.e. therapists without a postgraduate mental health qualification). Inclusion of the latter group within this review is harmonious with the findings of a Cochrane review which indicated no difference between professionals and paraprofessionals in effecting change within treatment outcomes of individuals with anxiety and depressive disorders (Boer *et al*. 2005).

Within the present review, guided self-help is defined as an individual's access to CBT-based self-help materials (e.g. books/manuals/internet) in the treatment of mild to moderate anxiety or depressive disorders, guided by the active support of a professional or paraprofessional therapist for no less than 30 minutes and no more than three hours in total. Studies in which therapist support consisted solely of reminders or assessment monitoring were excluded, as were studies which had less than a one month

follow-up evaluation. Studies without an appropriate control condition or with uninterpretable findings were also excluded.

Outcome measures

Studies assessing clinical effectiveness health outcomes via validated observer and/or self-report measurement tools of anxiety and depression were eligible for inclusion. If effect sizes for primary outcome measures comparing treatment and control groups at post-treatment and follow-up were not documented, they were calculated using the formula for Cohen's *d*:[(treatment mean – control mean)/pooled standard deviation].

Literature search strategies

Searches were limited to studies published in English due to lack of feasibility for translation of texts. The literature search was initially conducted in July 2009. The Cochrane Database of Abstracts of Reviews of Effects (DARE) was searched to verify that a similar review had not recently been conducted. To ensure this initial search was as comprehensive as possible, DARE was searched using the more inclusive term: 'self-help' as well as 'guided self-help' in addition to 'depressi*' OR 'anxiety'. This search revealed only two articles loosely pertinent to the current review: firstly, a Cochrane *protocol* (i.e. not a review) of brief media-delivered interventions for psychological problems (Mayo-Wilson & Montgomery, 2007); and secondly, a systematic review of randomised *and* non-randomised trials of self-help, i.e. not solely RCTs and not exclusively examining *guided* self-help (Bower *et al*. 2001).

Subsequently, screening of texts was conducted by searching the following electronic databases: PsycINFO (1990-2009); CINAHL (1990-2009); EMBASE (1990-

2009); and Medline (1990-2009). Searches were conducted within the domains of title, abstract and keywords. The following search string was used within each database: ('guided self-help' OR 'assisted self-help' OR 'facilitated self-help' OR 'supervised self-help' OR 'supported self-help' OR 'minimal intervention*' OR 'minimal contact') AND ('anxiety' OR 'depressi*'). These four databases were searched again using the same search string in May 2010 in order to account for any relevant articles published in the duration since July 2009 when the original literature search had been conducted.

Thereafter, to reduce any effect of publication bias, the first author contacted the primary authors of included studies and key review articles (e.g. Bower *et al*. 2001; Gellatly *et al*. 2007) to incorporate any unpublished studies which may meet inclusion criteria. Twenty-two authors were approached, of whom three could not be contacted and two did not respond. The seventeen responding authors suggested eighteen articles (both published and unpublished), but none of these met inclusion criteria for the current review. Additionally, relevant journals within the years of 2006 to 2009 were hand-searched: *British Journal of General Practice*; *British Journal of Psychiatry*; and *Psychological Medicine*. The search process (as detailed in Table 1) was completed by a manual search of each reference list from the included articles within this review, resulting in a total sample comprising 778 studies.

Table 1. *Summary of literature sources and resultant review articles*

Source of articles	Number of potentially relevant articles initially screened for inclusion	Number of articles included within this review	Review article number*
CENTRAL	34	3	8, 9 & 12
PsycINFO	67	4	6, 8, 9 & 11
EMBASE	79	5	6, 8, 9, 11 & 12
Medline	82	4	6, 8, 9 & 12
CINAHL	45	3	8, 9 & 12
Suggested papers after contacting relevant first authors	18	2	6 & 13
Hand-searching of relevant journals (2006-2009)	*British Journal of General Practice*: 9	1	12
	British Journal of Psychiatry: 5	2	4 & 5
	Psychological Medicine: 11	2	8 & 10
Manual search of reference list from included review articles	428	4	1, 2, 3, & 7
All sources	778	13	1 to 13

*: Review article numbers denote articles as follows: 1: Abramowitz *et al*. (2009); 2: Andersson *et al*. (2005); 3: Carlbring *et al*. (2006); 4: Carlbring *et al*. (2007); 5: Furmark *et al*. (2009); 6: Lovell *et al*. (2008); 7: Marks *et al*. (2004); 8: Mead *et al*. (2005); 9: Richards *et al*. (2003); 10: Salkovskis *et al*. (2006); 11: Schneider *et al*. (2005); 12: van Boeijen *et al.* (2005); 13: Warmerdam *et al*. (2008).

The titles and abstracts of the 778 potentially relevant studies were screened for initial assessment of their suitability according to inclusion and exclusion criteria, resulting in 41 studies. Upon further detailed reviewing of these studies, 28 studies were excluded for reasons outlined in Appendix 2. The final review was based on the remaining thirteen studies. Figure 1 illustrates the flow of the literature review process.

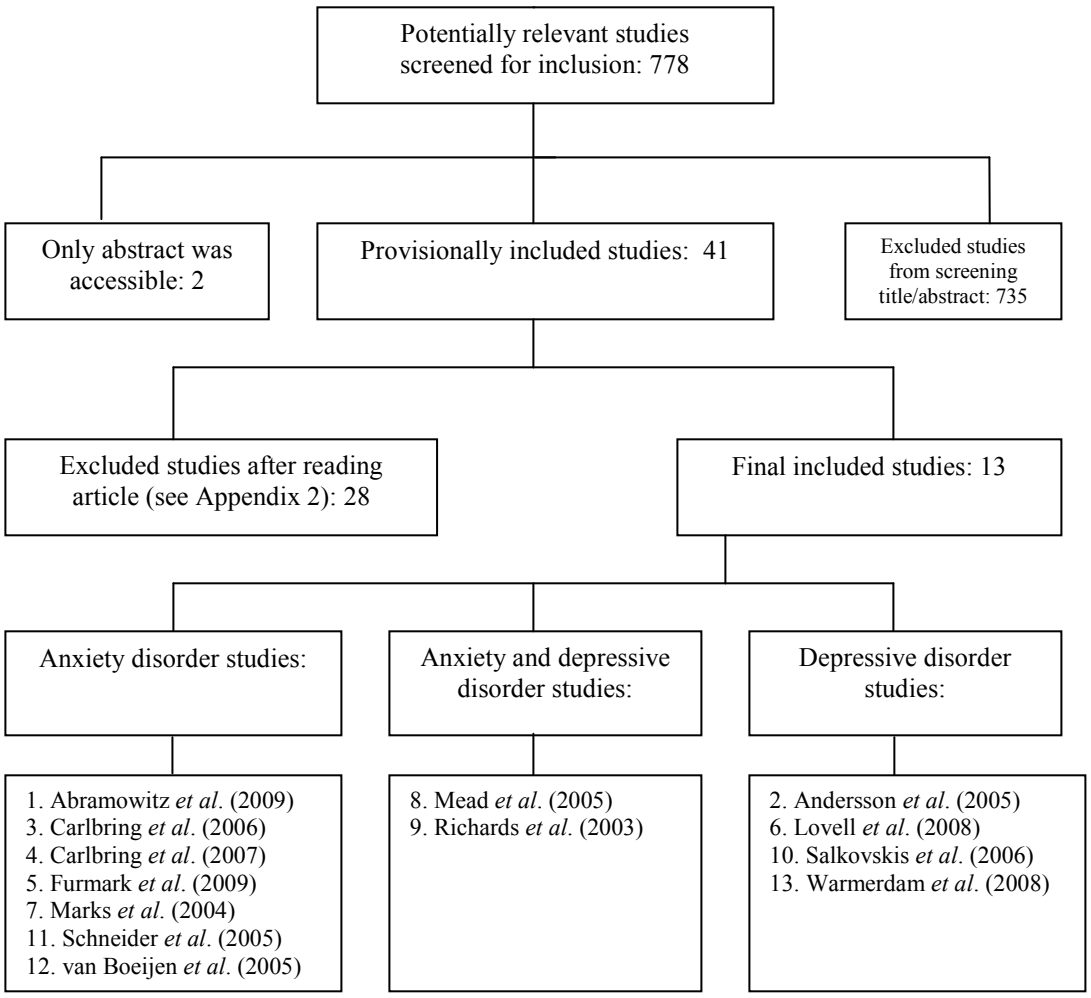

Figure 1. *Flow chart detailing the literature search process*

Assessment of quality of included studies

A recent Cochrane protocol (Mayo-Wilson & Montgomery, 2007) for media-delivered CBT for anxiety disorders in adults, concluded that "existing scales for measuring the quality of controlled trials have not been properly developed, are not well-validated and can give differing ratings of trial quality in systematic reviews". They advocate the *a priori* identification of relevant quality criteria which are pertinent to the specific review being conducted. The *Centre for Reviews and Dissemination* which is part of the National Institute for Health Research and has published internationally accepted

guidance on conducting systematic reviews in health care settings (CRD, 2008) recommends that quality criteria should encompass an assessment of: the risk of bias; the choice of outcome measure; statistical issues; quality of the intervention; and external validity (CRD, 2008). The CRD discuss assessing the *risk of bias* in terms of rating studies': process of randomisation; concealment of allocation; assessment of the similarity of groups at the study outset; reporting of the comparative level of attrition between groups; and use of intent-to-treat analysis. The CRD delineation of *choice of outcome measure* refers to the reliability and validity of measures therein, whilst *statistical issues* pertain to the sample size and subsequent power of the reviewed study. *Quality of the intervention* as outlined by the CRD refers to assessment of the extent to which the intervention was standardised and delivered as planned. Lastly, the CRD guide defines *external validity* in terms of the extent to which the study reflects how the intervention would be delivered within routine practice. The CRD document acted as a guide to limit the range of quality criteria to an optimal number which was both meaningful and workable to be able to draw generalisations from within a relatively narrow range of reviewed studies. Given consideration of the review topic, the current review encompasses a checklist of ten quality criteria identified *a priori*, which extend from the CRD guide to conducting systematic reviews and which encompass three overarching dimensions of quality criteria identified within the Delphi consensus (Verhagen *et al*., 1998) as being key: internal validity, external validity and statistical considerations. The list of quality criteria is outlined in full alongside Table 3.

The ten quality criteria were assessed in accordance with six outcome ratings as used by the Scottish Intercollegiate Guidance Network (SIGN) for assessing the

methodological quality of RCTs. The first author classified each quality criterion for each study in terms of one of the following six outcome ratings: 'well-covered' (2 points); 'adequately addressed' (1 point); and 'poorly addressed', 'not addressed', 'not reported' and 'not applicable' (all 0 points). The second author independently reviewed the quality of nine of the thirteen review articles, producing exact agreement on 78 per cent (70/90) of methodological quality ratings; the authors differed by one point (e.g. well-covered vs. adequately addressed) on 20 per cent (18/90) of items and by two points (e.g. well-covered vs. poorly addressed) on 2 per cent (2/90) of items. All criteria with differences between raters were reviewed and amended where appropriate.

Results

Characteristics of included studies

The thirteen studies identified for the review were all randomised controlled trials. Seven studies evaluated the effects of guided self-help upon anxiety disorders, four studies focused exclusively upon depression and two studies considered both anxiety and depression. Effect size calculations at pre-treatment indicated no differences between treatment and control groups in terms of primary outcome measures. Details of study characteristics and key findings are outlined in Table 2.

Table 2 *Characteristics, effect sizes and key finding of reviewed studies*

Study *Country*	Diagnosis	Gender (female)	Mean age at baseline (*SD*)	Intervention arms (N) at follow-up	Amount of therapist guidance (minutes)	Primary outcome measure	Follow-up period (months)	Recruitment method	Post-treatment Effect size (*Weighted)*	Follow-up Effect size *(Weighted)*	Key finding
Abramowitz *et al.* (2009) *USA*	Mild - moderate social phobia	76%	43.4 (*10.8)*	Guided self-help (11) Waitlist control (n/a)	180	BSPS	3	Media/Clinical	1.12 *(6.45)*	n/a	Self-help with minimal contact (therapist visit) group significantly superior to waitlist control group in terms of social anxiety symptoms at *post-treatment*.
Andersson *et al.* (2005) *Sweden*	Mild - moderate depression Mild - moderate panic disorder	78%	36.4 (*11.5*)	Internet CBT + emails + discussion group (36) Discussion group control (n/a)	60-90	BDI	6	Media	0.85 *(14.93)*	0.00 *(0.00)*	Internet-based therapy with minimal therapist contact group significantly superior to discussion waitlist control group at *post-treatment*.
Carlbring *et al.* (2006) *Sweden*		60%	36.7 (*10.0*)	Internet-guided CBT + weekly phone-calls (26) Waitlist control (n/a)	120	ACQ	9	Media	1.52 *(34.18)*	n/a	Internet-based self-help with minimal contact group significantly improved compared to waitlist control at *post-treatment*.
Carlbring *et al.* (2007) *Sweden*	Mild - moderate social phobia	59%	32.4 (*9.1*)	Internet-guided CBT + weekly phone-calls (27) Waitlist control (n/a)	95	LSAS	12	Media	0.98 *(15.37)*	n/a	Compared to waitlist control group, the internet-guided self-help group demonstrated significant improvement in social anxiety measures at *post-treatment*.
Furmark *et al.* (2009) *Sweden*	Social anxiety disorder	78%	35.0 (*10.2*)	Internet-guided CBT + weekly emails (36) Waitlist control (33)	135	LSAS	12	Media	0.78 *(12.57)*	0.25 *(4.34)*	Internet-guided self-help led to significant improvements in social anxiety compared to waitlist control group at *post-treatment*.
Lovell *et al.* (2008) *UK*	Mild - moderate (severe) depression	74%	37.6 (*12.4*)	Guided self-help (coaches) (19) GP treatment as usual (23)	132	BDI	3	Clinical	n/a	0.18 *(2.00)*	No significant difference between guided self-help group and usual care group in terms of BDI scores at *3-month follow-up*.
Marks *et al.* (2004) *UK*	Phobia and panic disorder	69%	38.0 (*12.0*)	Internet-guided + face-to-face (19) Relaxation (14)	120	Main Problem	3	Media/Clinical	1.38 *(15.55)*	n/a	Minimal contact internet-guided self-exposure was as effective as clinician-guided exposure therapy; both demonstrated significant change compared to relaxation control group at *post-treatment*.
Mead *et al.* (2005) *UK*	Mild - moderate anxiety/ depression	72%	38.7 (*10.7*)	Assistant guided self-help (50) Waitlist control (53)	60-120	HADS	3	Clinical	n/a	0.18 *(4.50)*	No significant difference between guided self-help group and waitlist control group on HADS at *3-month follow-up*.

Richards *et al*. (2003) *UK*	Mild - moderate anxiety depression	84%	39.2 (*12.6*)	Nurse guided CBT self-help (20) GP treatment as usual (21)	120-180	CORE	3	Clinical	0.49 *(4.54)*	0.31 *(3.03)*	Nurse guided self-help was not significantly more effective in terms of primary outcomes than GP usual care at *3-month follow-up*.
Salkovskis *et al*. (2006) *UK*	Moderate (severe) depression	78%	39.2 (*13.3*)	GP guided self-help (38) GP treatment as usual (39)	120-180	BDI	6	Clinical	0.14 *(0.41)*	0.03 *(0.62)*	No significant differences between guided self-help and GP usual care at *6-month follow-up*.
Schneider *et al*. (2005) *UK*	Phobias & panic disorder	74%	39.0 (*11.0*)	Internet-guided self-exposure (31) Internet-guided minimal CBT (13)	115 87	Main Problem	1	Clinical	0.10 *(0.11)*	0.39 *(3.81)*	At *1-month follow-up*, improvement was significantly greater if self-help included exposure instructions versus minimal CBT excluding exposure.
van Boeijen *et al*. (2005) *Netherlands*	Anxiety (GAD) panic	62%	38.8 (*12.7*)	GP guided self-help (53) GP guidelines (26)	100	STAI	9	Clinical	0.51 *(4.52)*	0.33 *(5.73)*	Guided self-help produced as much improvement as less structured GP guidance in terms of anxiety outcomes at *9-month follow-up*.
Warmerdam *et al.* (2008) *Netherlands*	Mild - moderate depression	71%	45.0 (*12.1*)	Internet/e-mail guided CBT (88) Waitlist control (87)	160	CES-D	1	Media	0.54 *(11.39)*	0.69 *(30.66)*	Internet-guided self-help was effective in significantly reducing depressive symptoms at *1-month follow-up* compared to waitlist control group.

ACQ: Agoraphobic Cognitions Questionnaire; BDI: Beck Depression Inventory; BSPS: Brief Social Phobia Scale;
CES-D: Center of Epidemiological Studies – Depression; CORE: Clinical Outcomes in Routine Evaluation;
HADS: Hospital Anxiety and Depression Scale; LSAS: Liebowitz Social Anxiety Scale; STAI: State-Trait Anxiety Inventory.

Quality of included studies

Table 3 provides ratings for each of the studies on the ten quality criteria. While the rating scale adopted does not provide an exact comparative measure across studies, it offers a guide to their relative methodological strengths. It suggests that Mead *et al*. (2005) and Salkovskis *et al*. (2006) conducted the methodologically strongest studies, while the majority of reviewed studies were of average quality overall.

As only four studies (Marks *et al*. 2004; Mead *et al*. 2005; Salkovskis *et al*. 2006; Warmerdam *et al*. 2008) explicitly reported details regarding the validity or reliability of their outcome measures, the authors independently examined the psychometric properties for all primary outcome measures outlined across the review articles. All measures appeared to be valid and reliable for the relevant populations. In terms of the statistical variables (i.e. quality criteria: vi; vii; and viii), one study appeared particularly robust (Salkovskis *et al*. 2006). This study, along with Andersson *et al*. (2005), Mead *et al*. (2005) and Schneider *et al*. (2005) were the only ones to be sufficiently powered. The degree of treatment fidelity applied to interventions was not reported for the majority of studies, although Mead *et al*. (2005) and Lovell *et al*. (2008) considered the impact of such integrity upon effectiveness outcomes.

Table 3 *Ratings of study quality for included studies*

Quality criteria	i) Randomisa-tion	ii) Allocation	iii) Baseline assessed	iv) Confounds controlled	v) Outcome measures	vi) Attrition	vii) Intention-to-treat	viii) Power	ix) Fidelity	x) Generalisa-bility	*Quality 'score'* (/10)
Study											
Abramowitz 2009	Not reported	Not reported	Well-covered	Adequately addressed	Not reported	Well-covered	Well-covered	Not reported	Adequately addressed	Poorly addressed	4.0
Andersson 2005	Adequately addressed	Adequately addressed	Not reported	Poorly addressed	Adequately addressed	Adequately addressed	Well-covered	Well-covered	Adequately addressed	Adequately addressed	5.0
Carlbring 2006	Well-covered	Not reported	Well-covered	Adequately addressed	Adequately addressed	Well-covered	Well-covered	Not reported	Adequately addressed	Poorly addressed	5.5
Carlbring 2007	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Adequately addressed	Well-covered	Well-covered	Not reported	Adequately addressed	Poorly addressed	6.0
Furmark 2009	Well-covered	Adequately addressed	Well-covered	Well-covered	Adequately addressed	Adequately addressed	Well-covered	Not reported	Adequately addressed	Poorly addressed	6.0
Lovell 2008	Well-covered	Well-covered	Adequately addressed	Adequately addressed	Not reported	Poorly addressed	Adequately addressed	Poorly addressed	Well-covered	Adequately addressed	5.0
Marks 2004	Well-covered	Well-covered	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Adequately addressed	Adequately addressed	Adequately addressed	Adequately addressed	7.0
Mead 2005	Well-covered	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Adequately addressed	Adequately addressed	Well-covered	7.5
Richards 2003	Well-covered	Well-covered	Well-covered	Adequately addressed	Not reported	Adequately addressed	Well-covered	Adequately addressed	Adequately addressed	Adequately addressed	6.5
Salkovskis 2006	Well-covered	Adequately addressed	Well-covered	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Well-covered	8.0

Schneider 2005	Well-covered	Adequately addressed	Adequately addressed	Adequately addressed	Poorly addressed	Adequately addressed	Adequately addressed	Well-covered	Adequately addressed	Adequately addressed	5.5
van Boeijen 2005	Well-covered	Adequately addressed	Well-covered	Adequately addressed	Not reported	Well-covered	Well-covered	Adequately addressed	Adequately addressed	Well-covered	7.0
Warmerdam 2008	Adequately addressed	Well-covered	Well-covered	Poorly addressed	Adequately addressed	Poorly addressed	Well-covered	Adequately addressed	Adequately addressed	Poorly addressed	5.0

i) The assignment of subjects to treatment groups is randomised.
ii) An independent concealment of allocation procedure is used.
iii) The treatment and control groups are similar at the start of the trial, with baseline scores described and differences assessed.
iv) The only apparent difference between groups is the treatment under investigation (i.e. adequate statistical control or adjustment for confounding factors).
v) Primary outcome measures are evidenced to be both valid and reliable and psychometric values are specified by the authors.
vi) Levels of attrition are reported and equivalent for treatment vs. control.
vii) Intention-to-treat (ITT) analyses are reported and missing values are imputed.
viii) A power calculation is reported and sufficient power is achieved.
ix) The intervention is both sufficiently defined and delivered as planned (i.e. demonstrates good fidelity).
x) Generalisability: the trial demonstrates external validity in terms of evaluating the intervention for an appropriate duration and within a clinically-relevant setting.

Six studies (Marks *et al*. 2004; Andersson *et al*. 2005; Carlbring *et al*. 2006; Carlbring *et al*. 2007; Abramowitz *et al*. 2009; Furmark *et al*. 2009) reported large effect sizes demonstrating effectiveness for guided self-help relative to controls at post-treatment. However, most of these studies were based upon media-recruited samples rather than samples recruited via mental health professionals and only one was sufficiently powered. Furthermore, the effectiveness of guided self-help relative to controls for these studies was typically either not reported at longer-term follow-up (Table 2), or indicated only a small effect size at follow-up (Furmark *et al*. 2009). In contrast, the studies which scored more highly on the methodological quality criteria (see the overall quality scores outlined in Table 3) tended to be based on clinical samples and mostly demonstrated limited or no effectiveness of GSH compared to controls, particularly at longer-term follow-up (ES = 0.18: Mead *et al*. 2005; ES = 0.03: Salkovskis *et al*. 2006). The methodologically strongest RCTs indicated that guided self-help did not lead to improved mental health outcomes in the longer-term (e.g. three months or more) with respect to waitlist control or GP usual care (Mead *et al*. 2005; Salkovskis *et al*. 2006).

Meta-analysis

Given the wide range of effect sizes across the reviewed studies and the suggestion of differential effectiveness dependent upon recruitment method and reporting of outcome at post-treatment versus follow-up, quantitative corroboration was sought via meta-analysis to gauge whether pooled effect sizes vary depending upon these factors. Within the meta-analysis, where studies reported more than one primary outcome measure, only

the first reported primary measure was chosen to ensure that no study was over-represented in the meta-analysis. The meta-analysis calculations were conducted by an external advisor who had experience of and access to software for conducting meta-analyses. The external advisor was provided with a database of all the relevant post-treatment and follow-up effect sizes for each reviewed study, as well as the sample size relevant for each calculation. The external advisor then provided the relevant output statistics, which were interpreted by the primary author, consisting of: weighted effect sizes for each study; overall weighted effect sizes; and Q-statistics indicating whether the extent of heterogeneity within the range of effect sizes was significantly greater than would be expected due to sampling variability.

Meta-analysis was conducted on 11 of the 13 reviewed studies reporting data post-intervention (Lovell *et al*. 2008, and Mead *et al*. 2005, did not report post-treatment data). Findings at post-treatment indicated a mean-weighted effect size of 0.69, suggesting considerable effectiveness of guided self-help compared to control conditions at post-treatment. However, seven of these 11 studies recruited participants primarily via media rather than clinical settings, with a mean effect size for media-recruited studies of 1.02, compared to a mean effect size for more clinically-representative studies of 0.31. The Q-test of homogeneity revealed significant heterogeneity amongst effect sizes ($Q = 29.13$, $df = 10$, $p < 0.01$), indicating greater variation than would be expected on the basis of sampling variability. Although further exploration of this heterogeneity and the potential effects of recruitment method would have been useful, the small N prohibited further detailed analysis.

Meta-analysis of effect sizes relating to differences between intervention and control groups was also conducted at follow-up and was feasible for nine of the 13 studies. The mean weighted effect size at follow-up of 0.32 was further reduced to 0.19 after excluding one study (Warmerdam *et al*. 2008) which had a low methodological rating and appeared to exert undue influence on the analysis. The Q-test of homogeneity at follow-up indicated no significant heterogeneity ($Q = 10.45$, $df = 8$, $p = 0.3$).

Discussion

This systematic review and meta-analysis conveys mixed findings for the effectiveness of guided self-help treatment for anxiety and depressive disorders. Whilst guided self-help seems significantly more effective than waitlist control conditions if one only considers outcomes immediately post-treatment amongst studies where participants were recruited primarily via media adverts, this effectiveness is less apparent amongst clinically-representative samples or at follow-up. The evidenced heterogeneity at post-treatment and apparent differences according to recruitment method suggest that the 'large' effects from media-recruited studies may not generalise to clinical practice settings. However, three of the six more clinically-representative studies included some participants with severe symptoms of depression or anxiety. As guided self-help is a 'low intensity' intervention intended for mild to moderate symptoms, the inclusion of individuals with severe symptoms may have undermined effectiveness within these studies. Regardless of recruitment method, the findings indicate that the extent of effectiveness of GSH in the longer-term is yet to be established.

The apparent finding that guided self-help interventions are less effective for patients recruited via primary care referrals compared to patients who self-select via media adverts is consistent with previous reviews of the depression literature (Churchill *et al*. 2002; Gellatly *et al*. 2007) and anxiety and depression more generally (Westen & Morrison, 2001). Gellatly *et al*. (2007) noted that the evidence base for self-help treatments for depression, identified within previous NICE guidelines (2004), stems almost exclusively from self-selected rather than clinical samples. Similarly, within the updated NICE guideline for depression (2009), the bulk of evidence proposed to support the effectiveness of GSH in reducing depressive symptoms when compared with waitlist control is based primarily on five studies (which were included within the 2004 NICE guideline as referred to by Gellatly *et al*. 2007) which are predominantly based upon self-selected rather than clinical samples. Seven of the thirteen included studies within the present review recruited some or all of their sample via media advertisements and self-selection. Such recruitment methods often rely on individuals' motivation levels, which potentially corresponds to a slightly different demographic from those participants who are recruited within primary care settings. Most of the methodologically stronger studies within the current review recruited research participants from clinical populations and generally demonstrated weak or non-significant effects of guided self help upon anxiety or depression, particularly where outcomes were considered at follow-up rather than only immediately post-treatment. The current findings highlight that the effectiveness of guided self-help within primary care settings as an effective treatment for anxiety and depressive disorders is not yet fully established and underlines the need for clinical recommendations to make

reference to the potential differential impact of recruiting people via media advertisements versus clinical practice.

A further issue which contributes to the ambiguity of GSH effectiveness relates to the degree of treatment fidelity within the reviewed studies. With the exception of Lovell *et al*.'s (2008) study which thoroughly addressed the issue of treatment fidelity, the remaining studies only partially addressed treatment fidelity in terms of sufficiently defining the intervention and reporting that it was delivered as planned. Of the 13 reviewed studies, only five explicitly mentioned that guided self-help therapists received GSH-specific training prior to applying GSH interventions. Furthermore, only six studies provided detail on whether therapists received supervision whilst guiding the intervention. Lack of detail regarding treatment fidelity, therapist training and therapist supervision reduces confidence in findings and generalisability of these studies – whether or not they endorse guided self-help as an effective intervention.

Strengths of review

The authors of this review attempted to limit the potential for publication bias by corresponding with authors of all included review articles, as well as authors of key relevant reviews in order to obtain any unpublished findings. The potential for subjective bias in methodological analysis was also limited by both authors independently rating the methodological quality of included review studies, producing a high degree of inter-rater reliability.

Limitations of review

The current review was restricted to articles published in English, some electronic databases were not included within the search and a necessarily finite number of search terms were explored, all of which may have inadvertently excluded potentially relevant studies.

Comparing and synthesising findings across a heterogeneous mix of mental health problems, amounts of guidance, outcome measures and follow-up periods was not straightforward and led to some inherent limitations. To minimise heterogeneity, the current review was confined to studies which met strict inclusion and exclusion criteria, such as limiting included studies to those with a therapist input of no less than 30 minutes and no more than three hours. Whilst some purported guided self-help studies have involved therapist input for a greater or lesser duration, for the purposes of definition and guided by recent relevant literature (e.g. Mead *et al*. 2005; Gellatly *et al*. 2007), the range of 30 minutes to three hours of therapist input was interpreted to be a proportionate amount of input representative of a *guided* self-help intervention. The review also excluded studies in which 'guidance' consisted simply of assessment or monitoring in order to conservatively assess the effectiveness of *guided* self-help. Whilst such definitions of guided self-help introduce an element of subjective bias, this delineation was necessary in order to afford a greater degree of specificity and transparency regarding the guided self-help interventions which were reviewed. It is acknowledged that by attempting to increase specificity, the resultant pool of reviewed studies was relatively small and the meta-analysis was based on only a small number of studies.

Implications for research, clinical practice and policy

Currently, a wide variety of formats and duration of therapist input are all defined as guided self-help, such that guided self-help interventions are interchangeably – though perhaps not systematically – defined within a whole host of varying terminology (e.g. self-help, minimal contact intervention and supervised self-help). The current review attempted to define guided self-help as clearly as possible, as an intervention: 'involving access to self-help materials in the treatment of mild to moderate anxiety or depressive disorders, guided by the active support (comprising more than reminders or monitoring) of a professional or paraprofessional therapist for no less than 30 minutes and no more than three hours in total'. Greater consensus regarding the definition of guided self-help and its distinction from non-guided self-help would facilitate future systematic evaluations of the effectiveness of such interventions.

Given the tendency within the current review for limited effectiveness of GSH at follow-up, amongst higher quality studies and amongst studies which recruited patients from clinical populations, it appears prudent to reserve judgement upon GSH effectiveness within clinical settings until the evidence base is substantiated by further high quality clinically-based research trials which examine longer-term effectiveness outcomes. This has implications for guideline panels and service managers. The NICE guidelines for depression (2009) currently recommend individual GSH for mild depression despite quite varied outcomes amongst studies with wide variations in terms of populations, recruitment, and study quality. Indeed, this heterogeneity is acknowledged within an appendix of those NICE guidelines, which concedes that across

five studies indicating evidence of GSH effectiveness, there is "serious inconsistency" with heterogeneity greater than 50 per cent. In addition, the effectiveness referred to within these five studies pertains to treatment end-point, not to follow-up. Together, such heterogeneity and lack of follow-up – highlighted within the current review as differentially impacting upon GSH effectiveness outcomes – underlines the importance of considering such factors when assessing the evidence base for the effectiveness of GSH. It seems essential for future GSH studies and subsequent guidance to utilise more specific, consensual definitions of GSH and to reflect more fully upon issues of heterogeneity, recruitment and follow-up to provide greater clarity regarding the effectiveness of specific types of intervention for specific populations.

As outlined within good-practice guidance of self-help within IAPT services (Baguley *et al*. 2010): "further research is required looking at the efficacy of self-help both across the range of disorders and also the manner in which it might be delivered (e.g. guided vs. unsupported)." While such low-intensity interventions clearly need to offer patients choice, many GSH studies could be more rigorous in terms of documenting treatment fidelity and providing training/supervision for guided self-help therapists. The introduction by IAPT of Psychological Wellbeing Practitioners (PWPs) who receive training and supervision, points toward greater standardisation. There is a need for appropriate evaluation and dissemination of clinical GSH services to facilitate understanding of efficacy and predictors of outcomes within the demands of clinical services. This would be aided by further qualitative research to inform our understanding of the relevance, acceptability and key components of GSH provision from the perspective of patients. It is likely that certain types of GSH provided by suitably trained

and supervised therapists would be effective for certain difficulties, but the evidence base does not yet provide this level of certainty.

It has been documented that there are "currently unrealistic assumptions about the proportion of patients who can benefit from guided self-help" (Lovell *et al*. 2008). More generally, Lucock *et al*. (2008) and Seekles *et al*. (2009) state the case for more effectiveness research within routine clinical practice in order to evaluate not only whether certain self-help interventions work, but crucially whether they work in clinical settings. The current review's findings highlight the possibility that GSH effectiveness outcomes are influenced by study quality, recruitment settings and timing of outcome; further underlining the importance of methodological rigour in future GSH effectiveness research. It seems reasonable to expect that GSH can be effective in certain formats for certain clients. Thus GSH should remain an integral component of stepped care, but in the context of a research focus which is more defined, agreed and scrutinised.

Lovell *et al*. (2008) indicate that more effective targeting of guided self-help interventions is required, with research into predictors or moderators of treatment effect, due to a current lack of understanding about who benefits from guided self-help. Research is beginning to indicate the impact of patient factors upon self-help more generally (e.g. MacLeod *et al*. 2009). Similarly, Lucock *et al*. (2008) and Williams and Martinez (2008) acknowledge that future studies should explore the impact of non-specific *therapist* factors upon self-help outcomes. While there is a suggestion that monitoring by the therapist is as effective as more structured guidance (Gellatly *et al*. 2007), further research (particularly with regard to anxiety disorders) exploring whether monitoring is as beneficial as active guidance to patients will be necessary to ensure the

provision of optimal levels of practitioner support within the low-intensity guided self-help interventions of the stepped care model. Greater understanding of the effective components of GSH and of the populations who genuinely benefit from such interventions is necessary to appropriately inform future evidence-based use of guided self-help within clinical practice.

Conclusions

This systematic review of the effectiveness of CBT-based guided self-help interventions for anxiety and depressive disorders suggests that the current reviewed evidence is inconclusive: guided self-help appears to be effective at post-treatment and within less clinically-representative populations, yet appears to be less effective within routine clinical settings and in the longer-term. Studies which have indicated greater effectiveness of CBT-based guided self-help within the current review have tended to be of poorer quality, have tended not to provide follow-up data and have been primarily based upon media-recruited participants rather than clinical samples. To ensure that clinical practice is informed by clinically-representative research findings and to help elucidate how effective guided self-help is for anxiety and depressive disorders, three aims for future research are suggested: i) greater consensus regarding what constitutes guided self-help; ii) more high quality studies which evaluate the effectiveness of well-defined guided self-help within representative primary care samples; and iii) more studies which report differences between treatment and control groups not only immediately following intervention, but crucially at longer-term follow-up intervals.

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2. RATIONALE FOR RESEARCH AIMS

The foregoing systematic review of CBT-based guided self-help effectiveness studies for anxiety and depressive disorders highlighted several key findings. Firstly, the evidence base regarding the effectiveness of *guided* self-help interventions for anxiety and depression within clinically-representative populations remains uncertain. Secondly, in contrast to self-selected, media-recruited populations, there are an insufficient number of controlled trials examining guided self-help effectiveness within clinically-representative, primary care settings. Thirdly, with current evidence primarily based on GSH effectiveness at post-treatment, there is a lack of evidence for GSH effectiveness outcomes in the medium or longer term. Fourthly, there remains a need to better understand the factors which may predict people's success with guided self-help. The current study aims to focus on these four aspects of the evidence base in an attempt to strengthen understanding of the effectiveness of GSH within primary care and provide insight into factors that may influence the likelihood of improvements in patients' mental health following GSH intervention.

Given the lack of evidence for GSH effectiveness in clinical settings and beyond post-treatment, the current study seeks to address the first three issues above by examining the effectiveness of guided self-help within a routine primary care setting and by examining outcomes not only at post-treatment but also at three and six month follow-up.

2.1 Factors predicting GSH outcomes

A more detailed pretext is required for the fourth aim, regarding factors that may predict successful GSH outcome, as this is not covered in detail within the systematic review. The evidenced discrepancy in effectiveness outcomes between clinical and non-clinical settings suggests that GSH can be effective, but it is difficult to gauge whether effective outcomes in self-selected, non-clinical settings are due more to specific factors intrinsic to GSH (e.g. the GSH manual which is used), or to common factors (e.g. factors not specific to the intervention such as self-efficacy or therapeutic alliance). As such, it may

be that these non-clinical studies are more indicative of efficacy than effectiveness, thereby limiting generalisability to clinical, primary care settings. Given the possible distinction here between evidenced efficacy in self-selected samples and a lack of evidence demonstrating effectiveness in clinical settings, it is worth investigating factors that may influence GSH effectiveness within clinical settings. It has been argued that much of the effectiveness seen within guided self-help may be due to non-specific factors (e.g. patient self-efficacy) rather than the self-help materials themselves (MacLeod *et al*., 2009). Given this lack of focus within the research field, the current study will investigate the role of a variety of factors that are non-specific to GSH, in influencing GSH effectiveness.

2.1.1 Therapeutic alliance

One common factor which exists within all interventions involving a therapist – such as guided self-help – is the therapeutic relationship. Therapeutic outcomes have been linked to the strength of the therapeutic alliance; a large meta-analysis of studies encompassing a variety of psychological therapies indicated an effect size of 0.22 between therapeutic alliance and outcome (Martin *et al*., 2000), and some authors argue that most of the systematic variance in patient outcomes in psychological therapies (i.e. all forms of therapy; not specifically self-help or guided self-help) can be explained by common factors such as therapeutic alliance (Messer & Wampold, 2002). Given the apparent greater effectiveness of 'guided' versus 'non-guided' or 'pure' self-help with regard to depressive disorders (Gellatly *et al*., 2007) - where the difference is the presence of a therapist - it seems reasonable to assume that non-specific factors such as therapeutic alliance could contribute significantly to guided self-help outcomes.

No quantitative literature currently exists on the impact of the therapeutic alliance on GSH outcomes for patients with depression and/or anxiety. While this may be due to a misconception that any therapeutic alliance in GSH is too brief to be validly assessed, the establishment of a positive therapeutic alliance has long been regarded as one of the *first* steps of therapy (Beck *et al*., 1979). Given the potential for such a significant role early within therapy, it follows that patients' and therapists' perceptions

or experiences of the therapeutic relationship could be influential in determining subsequent mental health outcomes, despite the patient and therapist only meeting for three or four appointments as is typically the case in guided self-help. Indeed, a qualitative synthesis of guided self-help studies suggested that the therapeutic relationship is fundamental in determining to what extent people engage with self-help materials (Khan *et al*., 2007). Given the potentially significant role of therapeutic alliance in contributing to GSH outcomes and the dearth of discussion of this within GSH literature, a primary objective of the current study was to quantitatively examine the impact of therapeutic alliance upon GSH outcomes.

2.1.2 Self-efficacy

A factor which has been evidenced to be predictive in the effectiveness of self-help more generally is patient self-efficacy (Mahalik & Kivlighan, 1988). Perhaps this is not surprising given that self-efficacy can be regarded as a source of motivation (Bandura, 1977) and it can be classed as a construct describing a person's belief in their ability to enact change through their own action in pursuit of goal attainment; two considerations which are liable to be intrinsic to guided self-help where the patient is required to take ownership of their therapeutic journey from the outset, albeit with some guidance from the therapist. A recent survey of mental health practitioners highlighted patient self-efficacy as one of the variables they identified to be most predictive of successful self-help outcomes (MacLeod *et al*., 2009).

However, with specific regard to *guided* self-help, research examining the impact of patient self-efficacy upon mental health outcomes is minimal. A recent guided self-help study found that self-efficacy was not predictive of mental health improvement (Hutchison, 2007). This finding was contrary to expectation given the findings of Mahalik and Kivlighan (1988) and the argument that greater self-efficacy would facilitate better engagement with self-help type interventions and thereby greater mental health improvement. Both studies were uncontrolled and were quite different in terms of therapist input, with the therapist having more input in structuring the intervention within Hutchison's study. However, the study of Mahalik and Kivlighan involved a

longer duration of intervention than that of Hutchison, which, alongside a greater onus on the patient, may have required greater patient motivation and therefore, necessitated a greater role for high self-efficacy. As such, it remains unclear to what extent patient self-efficacy affects patient outcomes, particularly with regard to guided self-help – as opposed to pure or non-guided self-help – where arguably, the person does not need to be self-reliant to the same extent. Due to the suggested implicit role of self-efficacy for guided self-help and given the greater effectiveness found for guided self-help within media-recruited versus clinical populations – in which motivation is liable to differentially affect engagement and outcomes – self-efficacy was investigated here in an attempt to determine whether it influences mental health outcomes following GSH intervention.

2.1.3 Socio-economic status

As GSH is an intervention within stepped care which aims to widen access to psychological support, it is important to ensure that the aim to match patient demand to service capacity on a broad scale is informed by a sound understanding of how demographic factors may influence the extent to which people initially access, engage with and then benefit from guided self-help. Despite the enduring presence of self-help and guided self-help interventions within the research literature, the potential role of patient characteristics in determining outcomes following these interventions remains under-explored (MacLeod *et al*., 2009). A comprehensive review discussing self-help interventions for mental health problems acknowledged that there has been minimal empirical study of socio-demographic factors which may facilitate a good response to self-help interventions (Lewis *et al*., 2003). Given this lack of evidence regarding the influence of demographic factors on mental health outcomes, particularly with specific regard to *guided* self-help, the current study aimed to discover the extent to which such a factor could be predictive of GSH outcomes.

It is well-documented that economic inequality, as indicated by lower socio-economic status (SES), is associated with poorer mental health outcomes (Scottish Executive, 2005). Successful outcomes for self-help (i.e. not *guided*) treatment of

depression have been connected with higher socio-economic status (Schmidt & Miller, 1983). Furthermore, a large survey of CBT psychotherapists identified 46.2 per cent of practitioners as believing socio-economic status to be an important factor in influencing self-help effectiveness (MacLeod *et al*., 2009). There is also evidence that adults of lower SES rate themselves more negatively in terms of their confidence, knowledge and skills to enact change which would lead to health improvement and sustained resilience during ongoing stress (Hibbard *et al*., 2004). This research suggests that there is a close link between a person's SES and their self-efficacy; both potentially contributing to ability to engage and benefit from psychotherapeutic interventions. Given the potential impact of lower SES in adversely impacting patients' access, engagement and completion of psychotherapeutic intervention, such non-engagement or defaulting of treatment within a substantial demographic would conflict with the broad remit of self-help type interventions in increasing the public's accessibility to psychological interventions within the stepped care model. Therefore, the current study aims to explore the role of socio-economic status in determining who does or does not engage with or benefit from being referred to primary-care GSH services.

2.2 Hypotheses

Hypothesis 1:

Primary care patients with mild to moderate anxiety and/or depression will show significant improvements in mental health and social functioning GSH outcomes at post-treatment relative to a control period, but these gains will not be maintained at 3- and 6-month follow-up.

Hypothesis 2a:

Patients experiencing a greater therapeutic alliance with their therapist will benefit to a greater extent from GSH in terms of improvement in mental health and social functioning.

Hypothesis 2b:

Patients with greater self-efficacy will benefit to a greater extent from GSH in terms of improvement in mental health and social functioning.

Hypothesis 2c:

Patients of higher socio-economic status will benefit to a greater extent from GSH in terms of improvement in mental health and social functioning.

Secondary research questions:

i) Do patients' views correspond with their therapist's views regarding the nature of their therapeutic alliance?

ii) Do patients have fewer contacts with services regarding their mental health in the three-month period following the guided self-help intervention compared to the three-month period prior to intervention?

iii) Do patients use a lower quantity of psychotropic medication in the three-month period following the guided self-help intervention compared to the three-month period prior to intervention?

3. METHODOLOGY

3.1 Participants

All adult patients (aged 18 upwards) whose primary care referral had been accepted within three Guided Self-help services across Lothian were eligible and invited to participate in the research. Eligibility was assumed in that only those people whose referral met inclusion and exclusion criteria of the GSH services would be considered for participation within the research. Appropriate referrals to the service comprised: low mood; mild to moderate anxiety and/or depression. If upon assessment, it transpired that the presenting problems were too complex to be targeted by GSH, their referral was passed up to a higher tier within the stepped care system.

Of 152 people referred to Service A*, 33 (21.7 per cent) provided informed consent and opted-in to the research. Of this number, one person was assessed to be inappropriate for GSH and so was excluded from the research. Eleven others defaulted treatment and thereby opted-out of the research, resulting in Service A data for 21 people who completed the guided self-help intervention. Of 351 people referred to Service B, 61 (17.4 per cent) provided informed consent and opted-in to the research. Two were assessed to be inappropriate for GSH and were excluded from the study. Of the remaining 59, 25 subsequently defaulted treatment and thereby opted-out of the research, resulting in Service B data for 34 people who completed the GSH intervention. Of 95 people referred to Service C, 6 (6.3 per cent) provided informed consent and opted-in to the research. Of this number, one person subsequently defaulted treatment and thereby opted-out of the research, resulting in Service C data for 5 people who completed the GSH intervention.

In summary, across the three guided self-help services, 100 people (16.7 per cent of the total number of people referred to the GSH services) opted-in to the research, of whom 3 people were excluded due to being inappropriate for GSH, 37 defaulted from the intervention and thereby the research, while 60 completed the guided self-help

* To maximise anonymity of participants, the three GSH services are referred to simply as Service A, B and C.

intervention. Figure 3.1 summarises the flow of participation and questionnaires administered across the study.

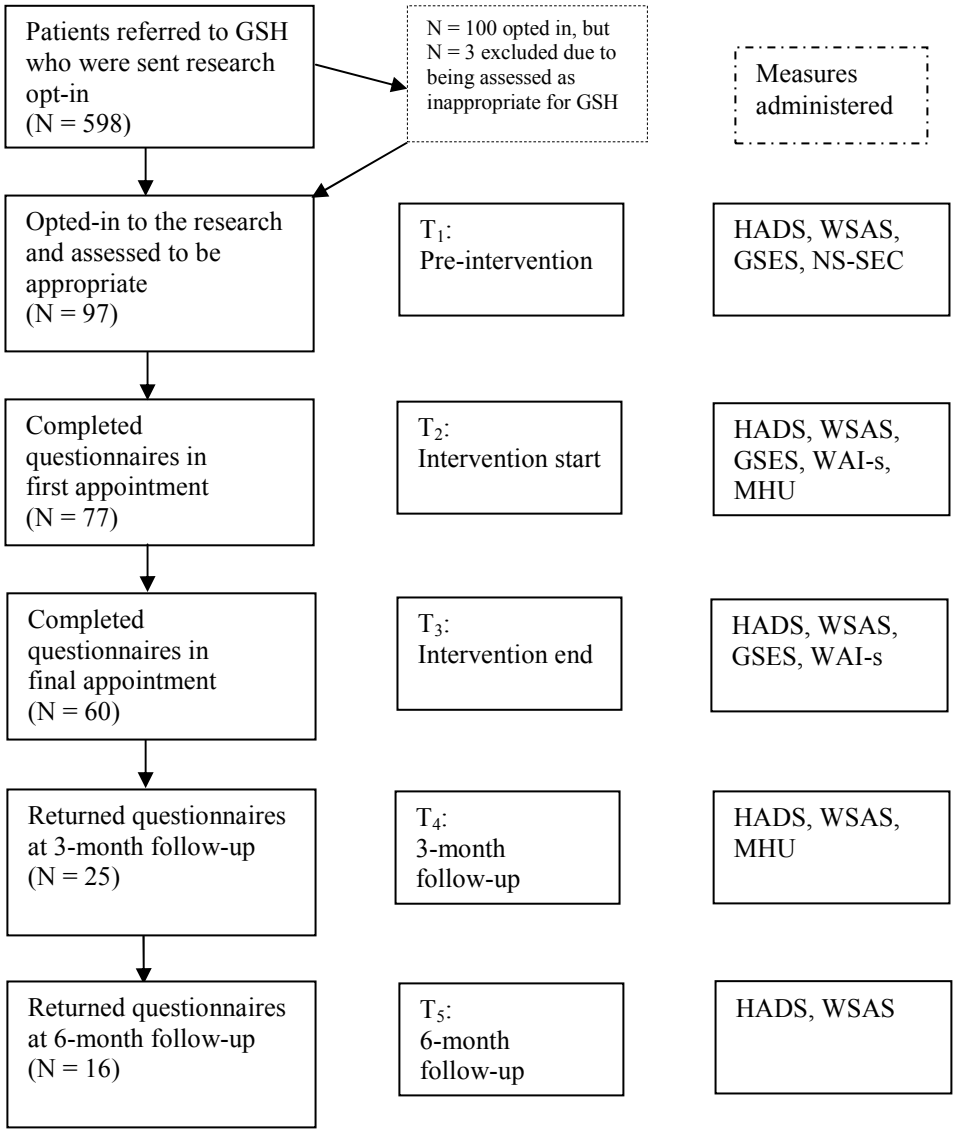

Figure 3.1 *Participant flow and measures administered across time*

3.2 Design

In an attempt to achieve treatment control while avoiding the ethical dilemma of denying patients an intervention, each research participant acted as their own control by receiving

their guided self-help intervention after a slight delay. Thus, each participant who opted-in to the study completed questionnaires approximately one month prior to beginning their GSH intervention. Administration of these questionnaires was repeated in the first session of the intervention and again – approximately one month later – during the last session of the intervention. Therefore, each research participant completed symptom measures at: one month prior to intervention (T_1 in Figure 3.1); intervention start (T_2); and intervention end (T_3). This design was adopted to provide control (i.e. T_2 - T_1) versus intervention (i.e. T_3 - T_2) periods which were comparable in order to control for any change in symptoms which may have happened spontaneously, irrespective of GSH intervention. If improvement in symptomatology across the intervention period was significantly greater than improvement across the control period, this would provide greater assurance that any mental health gains were due to intervention rather than spontaneous recovery. Thus, a within-subject design in which participants served as their own controls was used to examine any change in mental health or social functioning for the intervention versus control periods.

3.3 Procedure

Data were collected from patients within Service A between June 2009 and June 2011, within Service B between July 2010 and June 2011, and within Service C between January 2011 and June 2011.

All patients who met the inclusion criteria for the GSH service were sent information about the GSH service before being sent opt-in research questionnaire packs the following day. This opt-in pack consisted of a research information sheet (see Appendix 3) as well as a consent form (see Appendix 4) and baseline questionnaires comprising HADS, WSAS, GSES, NS-SEC (see Appendixes 5-8 as well as section 3.4 for psychometric details), to be returned in an enclosed, stamped, addressed envelope. If the consent form and questionnaires were not returned within approximately two weeks, it was assumed that that person had decided not to opt-in to the study. For ethical reasons, that person was not sent a reminder opt-in pack and no further contact was made.

For those people who did opt-in to the study, the date they completed the questionnaires (indicated on their returned consent form) signified the start of the control period. Where possible, a one-month control period was sought before the first session of the guided self-help intervention. The lead researcher received the initial opt-in questionnaires, while the GSH therapists administered the questionnaires within the first and last GSH sessions. Within the first session, the GSH therapist administered the HADS, WSAS and GSES at the beginning of the session. The participant was also asked to complete a brief, non-validated mental health utilisation (MHU) questionnaire consisting of four questions (see Appendix 9) regarding their prescription of psychotropic medication and consultation with GPs and other mental health professionals within the preceding three-month period. At the end of the first session, both the research participant and therapist completed their respective versions of the Working Alliance Inventory – Short version (WAI-s; Tracey & Kokotovic, 1989). In an attempt to obtain a fair representation of any alliance between therapist and patient, both parties were requested to complete this questionnaire in the absence of the other. To facilitate further data integrity, the patient was asked to seal - prior to the return of the therapist - their completed WAI-s in an envelope which was marked: "Private and confidential; only accessible to the lead researcher."

At the end of the final session of the intervention the GSH therapist again administered the HADS, WSAS and GSES. Again, the GSH therapist and patient completed their respective versions of the WAI-s. Finally, in order to examine any longer-term impact of GSH upon mental health and social functioning, the lead researcher sent the HADS and WSAS (as well as a stamped, addressed envelope) to research participants at follow-up intervals of three and six months subsequent to their final session of GSH intervention. At the three-month follow-up stage, participants were also sent the MHU questionnaire in order to ascertain the person's usage of psychotropic medication and GP consultations within the three-month period subsequent to their GSH intervention. If these follow-up questionnaires were not returned to the lead researcher, a reminder letter was sent - along with further copies of the questionnaires and stamped, addressed envelope - to the research participant. If this reminder letter did not result in

the return of the questionnaires, it was assumed that that person had opted-out of the research and they were not contacted further.

3.4 Measures

3.4.1 Therapeutic alliance

The 12-item Working Alliance Inventory (WAI-s; Tracey & Kokotovic, 1989) derives from the 36-item original version (WAI; Horvath & Greenberg, 1989). The WAI is one of the most frequently used and well-validated questionnaires assessing therapeutic alliance (Knaevelsrud & Maercker, 2006; Spinhoven *et al*., 2007). The original version has been shown to be reliable and valid and to correlate highly with other measures of therapeutic alliance (Summers & Barber, 2001). The WAI-s has been evidenced to have high interchangeability with the psychometric and predictive qualities of the full version of the form (Busseri & Tyler, 2003) and was included in the proposed research due to its brevity and capacity to capture both patient and therapist perspectives regarding their therapeutic alliance. There is strong evidence for both concurrent and predictive validity of the WAI-s (Tracey & Kokotovic, 1989). In a review of WAI-s studies, the WAI-s has been shown to have high internal consistency for the patient (.95) and therapist (.93) version, as well as high reliability for the patient (.97) and therapist (.92) version (Hanson *et al*., 2002).

The WAI-s is a self-report questionnaire, with patient and therapist versions, comprising three subscales which encompass three aspects of the therapeutic alliance. The level of agreement and engagement between the patient and therapist is assessed in terms of: the treatment goals; how to achieve the treatment goals; and the extent of acceptance, trust and confidence between the patient and therapist. Respondents are asked to rate each question on a 7-point Likert scale ranging from 1 (never) to 7 (always). A composite score (minimum: 12; maximum: 84) is used to provide a measure of the extent of the therapeutic alliance, with higher scores indicating a stronger therapeutic alliance.

3.4.2 Self-efficacy

Given the lack of a self-efficacy measure specific to mental health, the 10-item Generalised Self-Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995) was chosen to provide an indication of the participant's perceived ability to respond to difficult and emotional situations primarily by seeing the self as the agent of change. This scale is sufficiently broad to capture self-efficacy as a broad concept in predicting quality of life, well-being and health outcomes (Schwarzer & Hallum, 2008). In terms of psychometric properties, initial evaluations within German populations indicated high internal consistency (Schwarzer & Jerusalem, 1995). Subsequently, high validity and reliability have been reported across ethnically diverse samples and a range of research contexts (Luszczynska, Scholz *et al*., 2005). Factor analyses has indicated that the GSES forms one global dimension (Leganger *et al*., 2000) and the construct of self-efficacy has high convergent validity as indicated by significant correlations between GSES scores and factors synonymous with 'active coping' (Luszczynska, Scholz *et al*., 2005). Furthermore, significant inverse relationships have been identified between GSES scores and anxiety and depression (Leganger *et al*., 2000) while positive correlations have been evidenced between GSES scores and optimism (Luszczynska, Gutiérrez-Doña *et al*., 2005).

Participants respond to the GSES across 10 items (e.g. "I can remain calm when facing difficulties because I can rely on my coping abilities.") within a range of four responses from: (1) *not at all true* to (4) *exactly true*, culminating in a score ranging between 10 and 40 (higher scores indicating greater perceived self-efficacy).

3.4.3 Socio-economic status

Since 2001, socio-economic status has been indicated by a classification system based on a person's level of occupation (ONS, 2005). The occupation-derived National Statistics Socio-economic Classification (NS-SEC) system provides a contemporary representation of a person's socio-economic status and assigns people to social classes based upon their occupational title and level of responsibility within their employment.

It has been evidenced to have both criterion and construct validity, and is recommended for use as a standardised tool within research (Rose *et al*., 2005). This tool has been used to examine socio-economic classification within guided self-help research similar to the current study (Mead *et al*., 2005). A self-coded questionnaire version of NS-SEC exists which can be used in postal surveys (i.e. appropriate for the current study) and sub-classifies a person's status into one of five categories: managerial and professional occupations; intermediate occupations; small employers and own account workers; lower supervisory and technical occupations; and semi-routine and routine occupations. Based upon respondents' responses to four questions, it is possible to use this information to derive a classification of socio-economic status.

3.4.4 Mental health symptomatology

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a well-validated measure which provides an indication of the severity of symptoms of anxiety and depression. It has been evidenced to have high reliability and validity, with high internal consistency for the anxiety scale of .80 (Mykletun *et al*., 2001) and the depression scale of .84 (Cameron *et al*., 2008). It was used in this research due to: its brevity; its exclusion of somatic-based items which may otherwise artificially inflate scores; its wide use within primary care research; and its routine use within the services being researched.

The HADS consists of 14 self-report items: 7 anxiety and 7 depression symptom items, all of which are rated on a four-point Likert scale. Respondents are asked to rate their symptomatology within the preceding week, across four responses typically ranging from: (0) *not at all* to (3) *very often*. Within the anxiety and depression subscales, each has a possible total score of 21, with scores of 11 and above being indicative of clinically significant symptomatology.

3.4.5 Work and social functioning

The Work and Social Adjustment Scale (WSAS; Mundt *et al*., 2002) is a short, reliable and valid measure of functioning within work and social domains, with internal

consistency ≥ .80, convergent validity with depressive symptoms of .76, and good test-retest reliability (.73) (Mundt *et al*., 2002). Furthermore, the *Improving Access to Psychological Therapies* document (DoH, 2008) lists the WSAS within its 'Outcomes Toolkit' and recommends it as an outcome measure to implement within primary care outcome research.

Participants respond to the WSAS across five items relating to the domains of: work; home management; social leisure activities; private leisure activities; and family and relationships. Each item ranges from (0) *no impairment at all* to (8) *very severe impairment*, with high overall scale scores (maximum: 40) indicating greater functional impairment.

3.4.6 Mental health service utilisation

In order to further understand the effectiveness of guided self-help within the stepped care system, it was important to measure the impact of the intervention not only on the patient, but also on the wider health system surrounding the patient. In an attempt to gauge this service consumption, measurements were taken of participants' type and dosage of psychotropic medication prescribed (if any) and number of consultations with their GP and/or other mental health professional. A similar study conducted by Mead *et al*. (2005) measured these variables via self-report by research participants. This method of measurement was adopted in the current research by virtue of the mental health service utilisation (MHU) questionnaire consisting of four questions relating to participants' use of psychotropic medication and frequency of appointments with GPs or other professionals regarding their mental health within the preceding three-month period. Although this method provides ecological validity, there is a risk of losing valuable information due to the potential for social desirability in participants' responding or a memory lapse within participants' subjective recall. This risk was countered by attempting to assess participants' health service utilisation not only via subjective recall, but by objectively examining patient electronic records of the same information held within GP practices. It was anticipated that measuring participants' consumption of services in parallel in this way would provide a more robust reflection of

the impact of GSH intervention upon these variables than by solely asking participants to recall this information. Consultations between the patient and their GP (whether face-to-face or via telephone) were classed as a mental health consultation if the GP record for that consultation noted the patient's mental health issue exclusively or primarily, relative to any record of non-mental health issues.

3.5 GSH service characteristics

Participants were recruited from three different guided self-help services. These services received GSH referrals within primary care settings, either directly from general practitioners or via triage meetings. All services provided GSH intervention to adults with anxiety or depressive disorders, consisting of the therapist guiding the patient via written CBT-based self-help manuals. With regard to intervention for depressive problems, all services used the 'Overcoming Depression' (Williams, 2006) self-help resource. With regard to intervention for anxiety problems, GSH Services B and C typically used the 'Overcoming Anxiety' (Williams, 2003) self-help resource, while Service A used the 'How to Manage Anxiety' (Stuckey & Millar, 2003) self-help resource. Therapists within all three services guided patients using these self-help resources across no more than four sessions, depending on patient need, with each session typically lasting between 30 and 45 minutes.

Within Service B, four GSH therapists were employed concurrently to provide GSH interventions, compared to one GSH therapist employed in both Service A and C. Across the duration of data collection, the five therapists within Services B and C remained constant, while Service A consisted sequentially of three different therapists. All eight therapists had at least an undergraduate degree in psychology, with three educated to postgraduate level. In terms of professional qualifications, one GSH therapist had an MSc in Psychological Therapy in Primary Care, one therapist had a Post Graduate Certificate in Primary Care Mental Health, and one therapist had a Diploma in Counselling. Within services B and C, all therapists were designated 'guided self-help workers', while GSH Service A was provided by assistant psychologists. With regard to training prior to commencing the role, all therapists received induction into the GSH role

(i.e. encompassing the basics of CBT and the self-help manuals which were used) via psychologists working in clinical practice. Similarly, across the three services, all therapists received clinical supervision at least fortnightly from a practising psychologist, and a selection of guided self-help sessions were recorded and reviewed by supervisors to ensure treatment fidelity.

3.6 Ethical considerations

Ethical approval was given by the University of Edinburgh Ethics Committee. Ethical opinion was sought from the South East Scotland Research Ethics Service who classified the study as a service evaluation and thus did not require ethical panel review (see Appendix 10). Approval was also obtained from NHS Lothian Research and Development department and the Caldicott Guardian (see Appendixes 11 to 12).

One ethical consideration was participants' (and therapists') method of responding to the therapeutic alliance questionnaire (WAI-s). As this questionnaire sought to obtain patient and therapist perspectives upon the presence (or lack thereof) of any therapeutic alliance, in order to reduce the risk of receiving inflated responses through pressure to appear overtly harmonious, therapists were instructed to ensure that the patient and therapist both completed their respective version of the WAI-s in the absence of the other. Therefore, where possible, the therapist would briefly leave the patient in the clinic room so that both therapist and patient could complete the form independently of the other. Before temporarily leaving the clinic room, the therapist also asked the patient to seal their completed WAI-s within an envelope prior to the therapist returning. This envelope was marked: "Private and confidential: only accessible to the Lead Researcher." to emphasise to participants that their WAI-s responses would not be accessible to their therapist. These steps were taken in anticipation that patients (and therapists) could respond more truthfully and openly than may otherwise have been the case in the overt presence of the other member of the alliance.

Given the extensive questionnaire battery which participants were asked to complete across the duration of the research, questionnaires (where reliable and valid) were chosen for their brevity. Administration of the initial battery was piloted (piloting

indicated that 20 minutes would generally be a sufficient amount of time to complete the five measures) to ensure that the estimated time for completion outlined within the research information form was generally accurate. Piloting also indicated that it was likely that the 'Therapist' version of the WAI-s would take two to three minutes for therapists to complete.

Given the potential for participants to report significant distress during their GSH intervention, which would give cause for concern that GSH would not be a sufficiently intensive intervention for that person's needs, all GSH therapists were regularly supervised and could discuss such concerns with a qualified psychologist to ensure appropriate next steps. If such a discussion led to a research participant receiving a different intervention, then, by discontinuation of the GSH intervention, that research participant would take no further part in the research. Similarly, participants were reminded within the research information provided prior to consenting to the study that they could withdraw their participation at any point without a need for explanation and with no adverse consequences for their subsequent provision of psychological care.

3.7 Power analyses and statistical analyses

In order to detect differences between the intervention and control phases, with $\alpha = .05$ and a power value of .80, published power tables (Cohen, 1992) indicated that based on a medium effect size between two groups, a sample size would be required of n = 64. A medium effect size (around $d = 0.4$) was selected as an approximate average of the effect sizes of similar studies or meta-analyses, ranging from 0.19 (Mead *et al*., 2005) and 0.27 (Lucock *et al*., 2008) to 0.8 (Gellatly *et al*., 2007). With regard to the second hypothesis and which variables predict mental health or social functioning GSH outcomes, to detect a medium effect size ($f^2 = 0.15$) in multiple regression analyses with three predictor variables, with $\alpha = .05$ and power at .80, published power tables (Cohen, 1992) indicated that the required sample size would be 76 participants. Where necessary sample sizes were not achieved, post-hoc power calculations were conducted using an online statistical program (Soper, 2011).

To examine any changes between pre-and post-intervention mental health symptoms, frequency of mental-health based consultations and psychotropic medication quantities, paired-samples t-tests were used. Also, to incorporate non-completers of the intervention into analysis and to conservatively assess GSH effectiveness, intent-to-treat analyses were conducted using the last-observation-carried-forward (LOCF) technique. This technique carries forward pre-intervention scores to replace any missing values for outcome measures at post-intervention and has been used in similar GSH primary care research (e.g. Richards *et al*., 2003; van Boeijen *et al*., 2005).

Multiple regression analyses were used to explore the relative contribution of therapeutic alliance, patient self-efficacy and socio-economic status upon mental health and social functioning outcomes. Finally, to examine any correspondence between patients' and therapists' ratings of the therapeutic alliance, correlational analyses were used. Similarly, correlational analysis was applied to examine any correspondence between patients' subjective recall and GP records of mental health contact and medication usage.

4. RESULTS

4.1 Journal article results

4.1.1 General and demographic information

Of 598 people invited to participate, 100 (16.7 per cent) opted-in, three of whom were excluded as they were subsequently assessed to be inappropriate for GSH. Of the 97 people remaining, 72 (74.2 per cent) were female and ages ranged from 19 to 76 (*M* = 36.8; SD = 12.5). Of these 97 participants, 37 (38 per cent) defaulted treatment: 20 dropped out prior to the first GSH session and 17 defaulted after attending the first GSH session but prior to the final session. The remaining 60 participants completed the GSH intervention; 42 (70 per cent) of whom were female and ages ranged from 20 to 76 (*M* = 37.2; SD = 12.3). Thirty-two presented primarily with anxiety-related problems, while the remainder presented with depressive-related problems. Twenty-five participants received their GSH intervention across three sessions, while 35 received their intervention across four sessions. The mean duration of the baseline control period was 26.3 days (SD = 23.9) and 59.6 days (SD = 29.8) for the intervention period. At the time of analysis, 3-month and 6-month follow-up data were available for 25 and 16 participants respectively.

4.1.2 Effectiveness of GSH for anxiety and depression

The mean outcome scores for completers on the HADS and WSAS across the five time-points: pre-intervention (T_1); intervention-start (T_2); intervention-end (T_3); 3-month follow-up (T_4); and 6-month follow-up (T_5), are displayed in Table 4.1. Values were not imputed for missing data (e.g. where a questionnaire had mistakenly been overlooked by a participant); rather, to conservatively assess effectiveness and ensure transparency across the time-points, data were only analysed for each participant where measurements had been obtained at T_1, T_2, and T_3.

Table 4.1 *Anxiety, depression and functioning outcomes across time*

	HADS - Anxiety			HADS - Depression			WSAS		
	M	*SD*	n	M	*SD*	n	M	*SD*	n
Pre (T_1)	12.42	*3.05*	57*	8.16	*3.83*	57	19.64	*7.01*	44**
Start (T_2)	11.88	*3.71*	57	7.93	*3.80*	57	19.84	*7.32*	44
End (T_3)	8.19	*3.28*	57	4.74	*3.00*	57	14.77	*7.78*	44
3-month (T_4)	8.16	*4.31*	25	4.24	*2.95*	25	13.57	*8.02*	21
6-month (T_5)	9.44	*3.37*	16	5.06	*3.55*	16	14.00	*7.92*	14

* Not complete HADS data across T_1, T_2, and T_3 for n = 3, so removed from analysis.
** Not complete WSAS data across T_1, T_2, and T_3 for n = 16, so removed from analysis.

To ascertain whether these apparent improvements in mental health and social functioning across intervention and follow-up were significant compared to the control period, analyses examined whether symptom improvement by intervention-end (i.e. $T_3 - T_2$), 3-month (i.e. $T_4 - T_2$) and 6-month follow-up (i.e. $T_5 - T_2$) was significantly greater than any spontaneous improvement across the control period (i.e. $T_2 - T_1$). Therefore, paired t-tests were conducted to compare the degree of improvement by intervention-end, 3-month and 6-month follow-up to any degree of improvement across the control period (e.g. $T_3 - T_2$ versus $T_2 - T_1$). Table 4.2 displays the *t* and *p* values, as well as the effect size (Cohen's *d*) for each comparison. Across all three outcome measures, participants' outcomes improved significantly between the start and end of GSH intervention relative to the control period. Post-hoc power calculations at intervention-end indicated power of 0.92, 0.90 and 0.68 for anxiety, depression and social functioning improvement respectively. These significant improvements relative to the control period were maintained at 3-month follow-up, though the post-hoc power values across the three outcome measures ranged from 0.41 to 0.70. Despite a small sample size at 6-month follow-up, improvement in work and social functioning was also maintained but with a small power value (0.35).

Table 4.2 *Improvement in anxiety, depression and functioning across the intervention and follow-up compared to the control period*

	Intervention-end versus control period	3-month follow-up versus control period	6-month follow-up versus control period
HADS - Anxiety	*n* = 57 *t* = 4.20 ***p* < .01** *d = 0.91*	*n* = 25 *t* = 3.20 ***p* < .01** *d = 1.04*	*n* = 16 *t* = 1.99 *p* = .07 *d = 0.83*
HADS - Depression	*n* = 57 *t* = 4.22 ***p* < .01** *d = 0.88*	*n* = 25 *t* = 2.62 ***p* = .02** *d = 0.74*	*n* = 16 *t* = 1.75 *p* = .10 *d = 0.74*
Work/Social functioning	*n* = 44 *t* = 3.19 ***p* < .01** *d = 0.75*	*n* = 21 *t* = 2.67 ***p* = .02** *d = 0.80*	*n* = 14 *t* = 2.50 ***p* = .03** *d = 0.92*

To conservatively assess GSH effectiveness as indicated above, intent-to-treat (ITT) analysis using the last-observation-carried-forward (LOCF) technique was used to include those people who opted-in to the research but did not complete the GSH intervention. Therefore, for those people who defaulted GSH (n = 37), all pre-intervention or intervention-start scores were carried forward to post-intervention. Similarly, for those completers who had missing data (e.g. where a questionnaire had been mistakenly overlooked by the participant), LOCF was used to include these participants in the analysis. ITT analysis was based on 97 people (60 completers and 37 non-completers). Since the small sample size at follow-up would have resulted in ITT analyses at follow-up being based on estimation for the vast majority (74 per cent) of cases and therefore less meaningful, ITT analyses were conducted on post-intervention data only. Table 4.3 displays ITT mean and standard deviation statistics.

Table 4.3 *Anxiety, depression and functioning outcomes across time under ITT*

	HADS – Anxiety (N = 97)		HADS – Depression (N = 97)		WSAS (N = 91*)	
	M	*SD*	M	*SD*	M	*SD*
Pre (T_1)	12.16	*3.20*	7.79	*3.80*	18.69	*7.66*
Start (T_2)	11.73	*3.51*	7.60	*3.78*	18.70	*8.35*
End (T_3)	9.41	*3.71*	5.65	*3.54*	15.47	*8.67*

*N = 6 did not have WSAS data at pre-intervention or intervention start so could not be included via last-observation-carried-forward technique.

As Table 4.3 conveys, under ITT, the mean scores for all three outcomes at intervention-end (T_3) were still improved compared to intervention-start (T_2). To determine whether this improvement by post-intervention was significant compared to any spontaneous improvement across the control period, paired t-tests were conducted as displayed in Table 4.4.

Table 4.4 *ITT analysis of improvement in anxiety, depression and functioning across the intervention compared to the control period*

	Control		Intervention				
	M	*SD*	M	*SD*	*t*	*p*	Effect size (*d*)
HADS - Anxiety	0.43	*2.04*	2.32	*3.72*	3.91	**< .01**	0.63
HADS - Depression	0.19	*2.05*	1.95	*3.49*	3.94	**< .01**	0.61
Work/Social functioning	-0.01	*4.58*	3.23	*6.80*	3.52	**< .01**	0.56

The ITT analyses illustrate that even conservatively using the last-observation-carried-forward technique to accommodate missing data, significant improvements in mental health and social functioning occurred across the duration of the intervention relative to control, as evidenced by moderate to large effect sizes. Therefore, under ITT

conditions, mental health and social functioning outcomes are significantly improved at post-intervention.

4.1.3 Clinically significant change on HADS

As HADS subscale scores ≥ 11 typically indicate clinically significant symptomatology, the data of the 60 completers were examined to gauge what proportion of individuals experienced a clinically significant change in their symptoms. Of 38 people with clinically significant symptoms of anxiety at the start of GSH, 27 (71 per cent) no longer had clinically significant symptoms by the end of GSH intervention. Six of 15 (40 per cent) people no longer had clinically significant symptomatology by 3-month follow-up, while 6 of 9 (67 per cent) continued to enjoy clinically significant improved anxiety symptoms at six months. Of 7 people with clinically significant symptoms of depression at the start of GSH, 6 (86 per cent) no longer had clinically significant symptoms by intervention-end.

4.1.4 Factors influencing mental health and social functioning outcomes

As indicated previously, improvements in mental health (HADS) and social functioning (WSAS) were represented by calculating the difference in outcome scores between intervention start and end (i.e. $T_3 - T_2$). For the completer sample only, correlation and regression analyses were conducted to explore any relationships between these 'improvement scores' in mental health and social functioning, and self-efficacy, therapeutic alliance and socio-economic status. Significant correlations were found in the following instances: HADS (anxiety) improvement by intervention-end was inversely correlated with patient self-efficacy in the first GSH session ($r = -.39$, $p < .01$), positively correlated with patient self-efficacy in the final session ($r = .36$, $p < .01$), and positively correlated with patients' perception of the therapeutic alliance in the first session ($r = .27$, $p < .05$). HADS (depression) improvement by intervention-end was inversely correlated with patient self-efficacy in the first session ($r = -.34$, $p = .01$) and positively correlated with therapists' perception of the therapeutic alliance in the final

session (r = .29, p < .03). Improvement in social functioning was not correlated with self-efficacy, therapeutic alliance or socio-economic status.

Multiple regression analyses were conducted to further examine the relationships indicated by correlation analysis. Thus, for a regression model with improvement in anxiety by intervention-end as the outcome measure, three predictor variables (patient self-efficacy in first session; patient self-efficacy in final session; therapeutic alliance in first session) were entered into a stepwise regression analysis. The regression model was significantly predictive of outcome: $F(2, 50) = 23.68$, $p < .01$, explaining 48.6 per cent of variance in anxiety improvement. Two variables emerged as significant predictors: low patient self-efficacy as rated in the first GSH session ($\beta = -.66$, $t = 5.89$, $p < .01$) and high patient self-efficacy as rated in the final GSH session ($\beta = .63$, $t = 5.69$, $p < .01$). Collinearity statistics indicated that these two predictors loaded on to different dimensions, indicating that there was no presence of multicollinearity in the regression model. A post-hoc power calculation indicated that this regression model had a power value of 0.99 ($\alpha = 0.05$, two predictor variables, $R^2 = 0.49$).

Regarding improvement in depressive symptoms by intervention-end, as guided by correlation analysis, patient self-efficacy in the first session and therapeutic alliance in the final session were entered into a stepwise regression analysis. The regression model was significantly predictive of outcome: $F(2, 51) = 6.40$, $p < .01$, explaining 20.1 per cent of variance in depression improvement. Two variables emerged as significant predictors: therapeutic alliance as rated by the therapist in the final session ($\beta = .30$, $t = 2.37$, $p = .02$) and low patient self-efficacy in the first GSH session ($\beta = -.29$, $t = -2.30$, $p = .03$). Again, collinearity statistics highlighted that these two predictors loaded on to different dimensions, indicating that there was no presence of multicollinearity in the regression model. A post-hoc power calculation indicated that this regression model had a power value of 0.91 ($\alpha = 0.05$, two predictor variables, $R^2 = 0.20$).

4.2 Additional results

4.2.1 Normality

Kolmogorov-Smirnov statistics and normal Q-Q plots indicated some deviation from normality within the intent-to-treat dataset for a minority of outcome variables (i.e. improvements in anxiety, depression, and social functioning) where due to last observations being carried forward, there were no differences between symptoms at start and end of the intervention for non-completers; i.e. multiple data-points had a value of 0. Nonetheless, non-parametric analyses (e.g. Wilcoxon Signed-Rank tests and Spearman's rho) were conducted as a conservative equivalent to confirm that parametric analyses were not unduly influenced by any non-normality.

4.2.2 The role of therapeutic alliance in GSH

Secondary research question i): Do patients' views correspond with therapists' views regarding the nature of their therapeutic alliance?

Pearson correlations were analysed to examine whether patients' views corresponded with therapists' views regarding the nature of their therapeutic alliance. As Table 4.5 indicates, patients' and therapists' views regarding the therapeutic alliance were not significantly correlated in the first GSH session, but they were significantly correlated within the final GSH appointment. Akin to the significant correlation between patients' views on the therapeutic alliance in the first and last appointments, therapists' views on the therapeutic alliance in the first and last appointments were also significantly correlated.

Table 4.5 *Correspondence between patients' and therapists' ratings of the therapeutic alliance*

	WAI-Start Patient	WAI-Start Therapist	WAI-End Patient
WAI-Start Therapist	*r* = .03 *p* = .82		
WAI-End Patient	*r* = .42 ***p* < .01**	*r* = .13 *p* = .36	
WAI-End Therapist	*r* = .13 *p* = .35	*r* = .26 ***p* < .05**	*r* = .45 ***p* < .01**

A univariate (2 x 2) ANOVA was conducted to explore the impact of time (intervention start *versus* intervention end) and grouping (patient *versus* therapist) on rated therapeutic alliance. Both grouping and time were found to be significantly related to mean therapeutic alliance ratings: Group, $F(1) = 20.72$, $p < .01$; Time, $F(1) = 15.11$, $p < .01$. As depicted graphically in Figure 4.1, the interaction between group and time was not significant: $F(1) = 0.01$, $p = .93$.

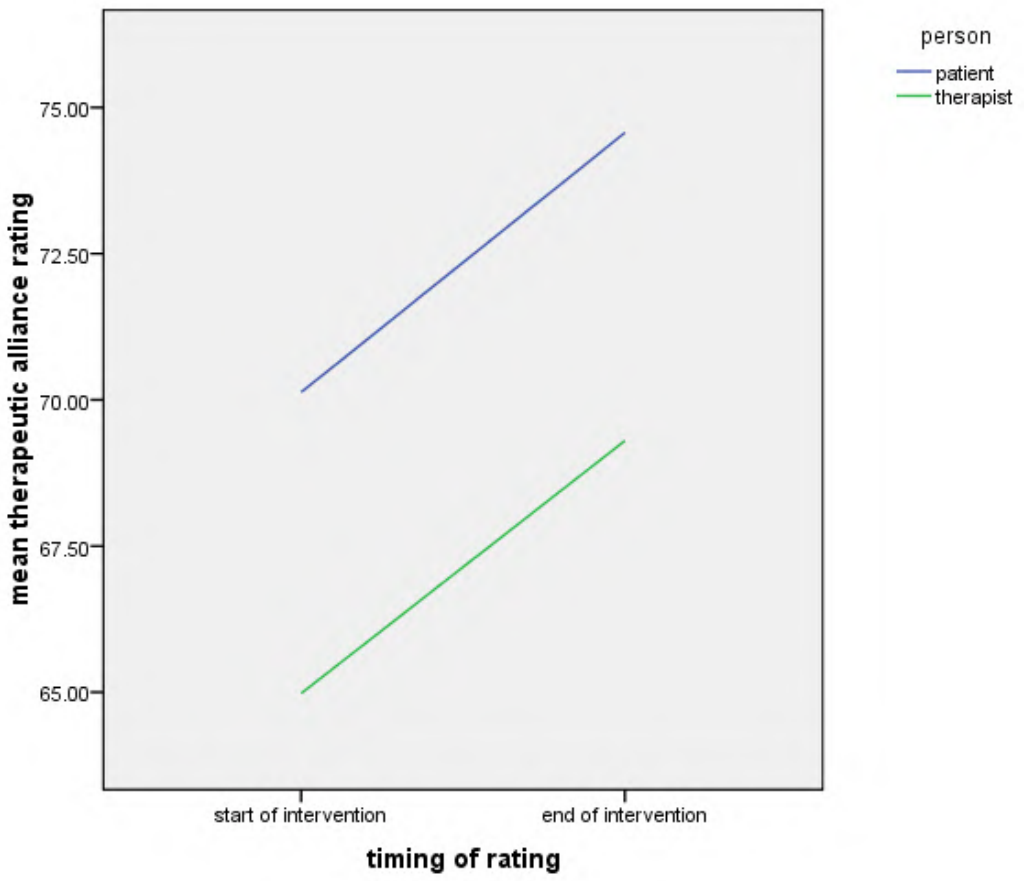

Figure 4.1 *Therapeutic alliance as rated by patients and therapists across time*

Finally, with regard to the apparent discrepancy between patients' and therapists' ratings of the therapeutic alliance, correlations were examined to determine whether the discrepancy between therapist and patient ratings in the first GSH session or in the last session was related to any improvement in mental health or social functioning by the end of intervention. No significant correlations were identified between the discrepancies in therapeutic alliance ratings and mental health or social functioning improvement (all $p >$ .20).

4.2.3 The wider impact of GSH on primary care services

Secondary research question ii): Do patients have fewer contacts with services regarding their mental health and use a lower quantity of psychotropic medication in the three-month period following the guided self-help intervention compared to the three month period prior to intervention?

3-month follow-up data regarding patients' frequency of mental health consultations with GPs or other mental health professionals was obtained for 26 of the 60 completers. In the 3-month period preceding the GSH intervention, patients visited their GP regarding their mental health problems on a mean number of 2.96 occasions (SD = 2.36) and other professionals (e.g. counsellor, community psychiatric nurse, psychiatrist) on a mean number of 0.29 occasions (SD = 0.90). In contrast, in the 3-month period following GSH intervention, patients visited their GP regarding their mental health on a mean number of 0.92 occasions (SD = 1.20) and other professionals on a mean number of 1.10 occasions (SD = 3.06). These contrasts are depicted graphically in Figure 4.2. The difference in the mean frequency of patients' consultations with their GP before and after GSH intervention was statistically significant: $t(25) = 4.29$, $p < .01$, while the corresponding difference between time periods with regard to consultation with other mental health professionals was not significant: $t(20) = 1.13$, $p = .27$.

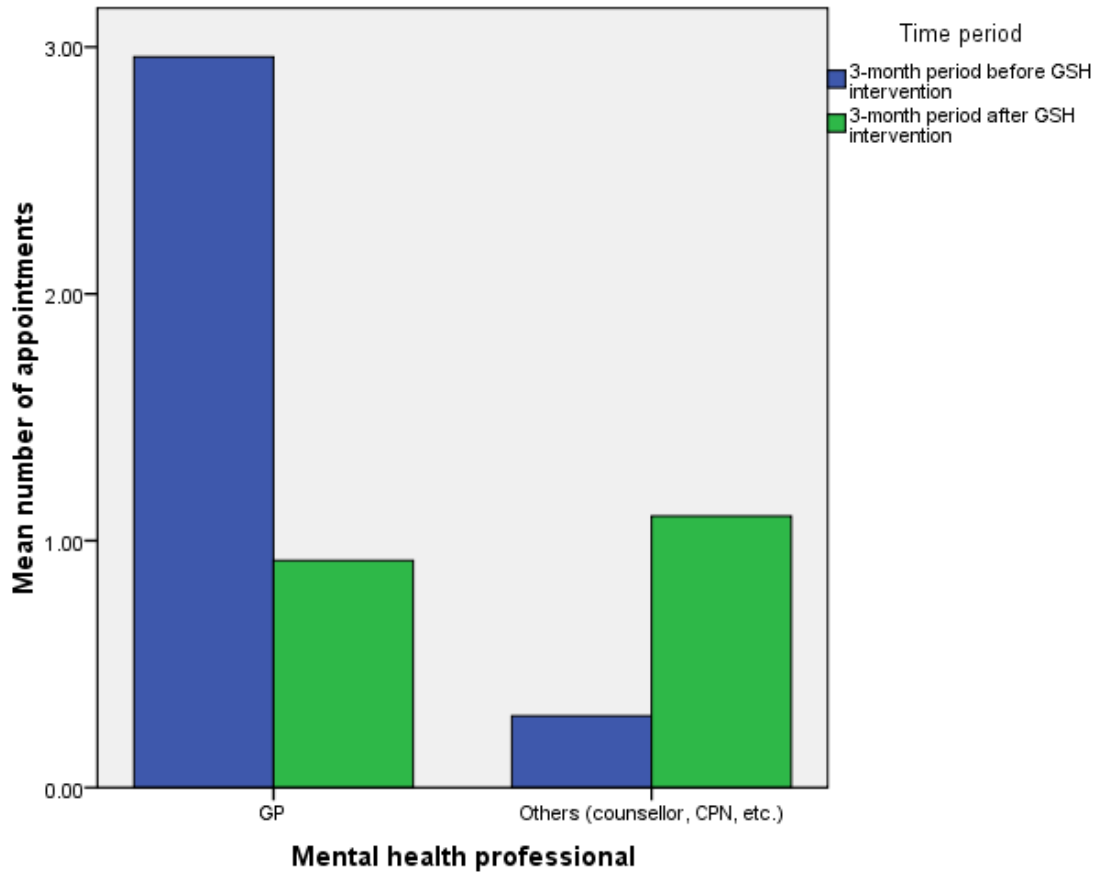

Figure 4.2 *Completers' consultations regarding their mental health*

With regard to the prescription of psychotropic medication, 9 of the 26 participants were not prescribed medication in either of the 3-month periods. Within the remaining 17 patients, 10 remained on the same type and dosage of medication (e.g. citalopram, fluoxetine, etc.) in the 3-month period following GSH intervention as was received in the 3-month period preceding the intervention; 6 people received a lower quantity of psychotropic medication following GSH intervention; and the remaining person saw their psychotropic prescription increase in dosage following GSH intervention.

4.2.4 Differences between GSH completers and non-completers

An independent samples t-test was used to examine any differences in baseline scores between those who completed the intervention (n = 60) and those who defaulted from GSH prior to completing the intervention (n = 37). The array of variables for the two groups with corresponding means, standard deviations, *t* and *p*-values are outlined in Table 4.6. As can be seen, only one variable, socio-economic status ($t = -2.05$, $p < .05$), significantly (albeit marginally) distinguished those who completed the intervention from those who defaulted the intervention. Specifically, completers had a significantly higher socio-economic classification, indicating they were more likely to have managerial or professional occupations, whereas non-completers were typically more likely to have routine or technical occupations.

Table 4.6 *Differences between completers and non-completers on baseline variables*

Baseline variable	Completers (n = 60)		Non-completers (n = 37)			
	M	*SD*	M	*SD*	*t*	*p*
Age	37.15	*12.27*	36.1	*12.91*	0.39	.70
SES	1.62	*1.10*	2.3	*1.62*	2.05	**.047**
HADS-A (Pre)	12.30	*3.12*	11.9	*3.35*	0.53	.60
HADS-D (Pre)	8.03	*3.81*	7.3	*3.79*	0.82	.41
WSAS (Pre)	19.26	*7.93*	17.7	*7.16*	0.94	.35
GSES (Pre)	24.67	*5.63*	24.4	*5.74*	0.20	.84
Therapeutic alliance (Patient)	68.82	*13.54*	66.2	*10.04*	0.78	.44
Therapeutic alliance (Therapist)	63.72	*11.83*	65.3	*5.80*	0.59	.56

4.2.5 Differences in mental health and social functioning between GSH services

To check that the GSH intervention received between services was equitable in terms of effectiveness, two of the three services were compared to examine if there were any differences in the extent of improvement in mental health and social functioning. At the time of analysis, Service C had insufficient completers to warrant analysis (n = 5).

Independent samples t-tests were used to analyse the differences between the other two services (A, n = 21; B, n = 34) and these data are outlined in Table 4.7. As conveyed in Table 4.7, the services did not differ significantly in terms of the improvements observed across any of the outcome measures.

Table 4.7 *Differences in improvement between two GSH services*

Outcome measure	Service A		Service B		*t*	*p*
	M	*SD*	M	*SD*		
HADS – Anxiety (By end of intervention)	2.33	*3.23*	4.16	*3.83*	1.80	*.08*
HADS – Anxiety (By 3-month follow-up)	3.20	*4.02*	4.00	*3.41*	0.51	*.62*
HADS – Depression (By end of intervention)	3.00	*4.15*	3.06	*3.92*	0.06	*.96*
HADS – Depression (By 3-month follow-up)	2.70	*3.62*	2.42	*2.19*	0.22	*.83*
Work/Social functioning (By end of intervention)	4.13	*8.59*	6.69	*8.30*	0.94	*.35*
Work/Social functioning (By 3-month follow-up)	5.44	*8.95*	4.90	*5.38*	0.16	*.88*

4.2.6 Differences in mental health and social functioning between those on medication and those not on medication

Of the 60 completers, at the beginning of the intervention 28 patients were receiving psychotropic medication relevant to their mental health problem, while 26 did not have a prescription for psychotropic medication (the remaining six did not indicate either way). To examine whether any of the improvements in mental health or social functioning may have been attributed to the effect of medication, independent samples t-tests were conducted to compare the outcomes of those on medication versus those without

medication across the various measures at post-intervention and 3-month follow-up. Table 4.8 displays that irrespective of the person's psychotropic medication status, the degree of improvement across all outcomes at post-treatment and 3-month follow-up was not significantly different.

Table 4.8 *Differences in mental health and functioning improvement between those on medication and those not on medication*

Outcome measure	On medication (n = 28)		No medication (n = 26)			
	M	*SD*	M	*SD*	*t*	*p*
HADS – Anxiety (By end of intervention)	3.68	*4.56*	3.69	*4.10*	0.01	*.99*
HADS – Anxiety (By 3-month follow-up)	3.64	*3.82*	3.63	*3.54*	0.01	*.99*
HADS – Depression (By end of intervention)	4.00	*4.27*	2.38	*3.97*	1.43	*.16*
HADS – Depression (By 3-month follow-up)	2.50	*3.13*	2.63	*2.50*	0.10	*.92*
Work/Social functioning (By end of intervention)	5.43	*7.36*	6.04	*9.59*	0.24	*.81*
Work/Social functioning (By 3-month follow-up)	4.92	*5.76*	5.57	*9.45*	0.19	*.85*

4.3 Summary of results

Effectiveness of GSH for anxiety and depression

Relative to a control period, GSH intervention led to significant improvement in mental health and social functioning outcomes by post-intervention, even under conservative ITT conditions. Analysis of the completer sample revealed that improvements in mental

health and social functioning were maintained at 3-month follow-up, and improvement in social functioning was maintained at 6-month follow-up. The vast majority of completers experienced clinically significant change at post-treatment, and these gains were generally maintained at follow-up, despite small numbers.

Factors influencing mental health and social functioning outcomes

Improvement in anxiety symptomatology was correlated with low self-efficacy in the first GSH session, high self-efficacy in the final session, and greater therapeutic alliance as rated by the patient in the first session. Improvement in anxiety symptomatology by the end of intervention was predicted by a regression model consisting of low self-efficacy in the first session, and high self-efficacy in the final session.

Improvement in depressive symptomatology was correlated with low self-efficacy in the first GSH session and greater therapeutic alliance as rated by the therapist in the final session. Improvement in depressive symptomatology by the end of intervention was predicted by a regression model consisting of therapist-rated therapeutic alliance in the final session and low patient self-efficacy in the first session.

The role of therapeutic alliance in GSH

Patient and therapist ratings of the therapeutic alliance were unrelated at the start of the intervention, though became significantly correlated by the end of intervention. Therapeutic alliance was rated significantly more positively by both patient and therapist at the end compared to the start of intervention. Therapeutic alliance was rated significantly more highly by completing patients than by their therapists. Discrepancies in therapeutic alliance ratings between patients and therapists were not related to improvements in mental health or social functioning.

The wider impact of GSH on primary care services

Patients saw their GPs for significantly fewer appointments regarding their mental health in the three month period following GSH intervention compared to the three month

period preceding their intervention. Patients consulted with other professionals regarding their mental health slightly more following GSH, but not significantly so.

Differences between GSH completers and non-completers

The only baseline variable which distinguished completers from non-completers was socio-economic classification such that those participants from a higher socio-economic classification were significantly more likely to complete the GSH intervention than those participants from a lower socio-economic classification.

Differences in mental health and social functioning improvements between GSH services

With regard to improvements in anxiety, depression, and work and social functioning at the end of GSH intervention and at 3-month follow-up, there were no significant differences between two different GSH services, suggesting that both services were comparable in terms of their effectiveness.

Differences in mental health and social functioning improvements between those on medication and those not on medication

The prescription of psychotropic medication prior to GSH had no bearing on the degree of improvement in mental health across the GSH intervention compared to those who had not been prescribed psychotropic medication, indicating that GSH can be effective independently of psychotropic medication.

5. DISCUSSION

This chapter will discuss the key findings relating to the study's central hypotheses and secondary research questions, in the context of the literature critiqued within the systematic review of Chapter 1 and other relevant literature. The key findings will be considered in relation to the strengths and limitations of this study, before widening the discussion to reflect on the implications of the current findings for clinical practice and policy, and to suggest directions for future research.

5.1 Effectiveness of GSH for anxiety and depression

Hypothesis 1a: Patients with mild to moderate anxiety and/or depression will show significant improvements in mental health and social functioning at post-treatment relative to a control period.

Patients' mental health and social functioning outcomes were significantly improved by post-treatment upon completion of their GSH intervention. This finding was further corroborated by the large effect sizes demonstrating the improvement across the duration of the intervention. These large effect sizes are consistent with those found in a recent, large-scale cohort study evaluating low-intensity interventions such as GSH in two *Improving Access to Psychological Therapies* (IAPT) sites (Clark *et al*., 2009). The significant improvements observed within the completer sample were obtained even within conservative intent-to-treat (ITT) conditions, although the corresponding effect sizes under ITT were more moderate as would be expected. In comparison to the reviewed GSH studies within Chapter 1, the post-treatment effect sizes obtained here under ITT are generally midway between the large post-treatment effect sizes typical of non-clinical GSH studies (e.g. Andersson *et al*., 2005; Furmark *et al*., 2009) and the small effect sizes typical of clinical GSH studies (e.g. Mead *et al*., 2005; Salkovskis *et al*., 2006). Of the studies reviewed within Chapter 1, the post-treatment ES is comparable to the clinical-based study of Richards *et al*. (2003); $d = 0.49$, and the non-clinical based study of Warmerdam *et al*. (2008); $d = 0.54$. Under ITT, the former study

found that nurse-guided CBT self-help was not any more effective than ordinary GP care, while the latter study found that internet-based CBT was effective in reducing depressive symptoms compared to waitlist control. Therefore, the current study demonstrates effectiveness of GSH to a greater extent than the previously reviewed clinical studies but to a lesser extent than the reviewed non-clinical studies (other than Warmerdam *et al*., 2008).

Some of the discrepancy between the current study and the clinically-representative studies reviewed within Chapter 1 may be due to the non-randomised design and lack of a distinct control group within the present study. In light of this, the current findings were examined in the context of more comparable GSH studies (e.g. Farrand *et al*., 2008; Lucock *et al*., 2008; Lucock *et al*., 2011). The study of Farrand *et al*. found that GSH was effective in reducing HADS anxiety and depressive symptomatology from baseline (both $p < 0.01$), but the study was uncontrolled and did not report an effect size (ES). Compared to the current study, Lucock *et al*. (2008) found a smaller ES ($d = 0.27$) for improvement in anxiety symptoms, but their lower ES may be due to the guidance consisting of only 40 minutes, in contrast to a range of 90 to 160 minutes of guidance in the current study. More recently, Lucock *et al*. (2011) conducted a pragmatic randomised controlled trial of GSH for anxiety and depression in a clinical setting and found a similar ES ($d = 0.38$) to the current study. Therefore, the current study adds to the evidence base by being one of only a few studies which has demonstrated GSH effectiveness within a clinical setting. Possible reasons for the higher effect sizes observed in the current study may include: milder baseline symptomatology; different self-help manuals being differentially effective; and the lack of a distinct control group.

By having a control period prior to introduction of the intervention, in which each participant served as their own control, the likelihood is increased that the mental health and functioning improvements are due to the GSH intervention. However, it should be noted that the improvement in anxiety symptoms across the duration of the control period approached significance ($t = 1.77$, $p = .08$). This suggests that further time without intervention may have led to further reduction in symptomatology, particularly

given the potential for spontaneous remission of mild to moderate mental health symptoms (Posternak & Miller, 2001). While these findings encourage caution in interpreting the extent to which improvements in anxiety symptomatology were due to the intervention, it remains true that those who completed GSH had significantly improved symptomatology by the end of intervention compared to the control period and these changes were associated with large effect sizes. Differences in medication seem unlikely to explain this improvement as the degree of improvement across all outcome measures was not differentially influenced by medication status (i.e. those receiving *versus* those not receiving psychotropic medication at the start of intervention). Therefore, there seems to be some direct result of the person's completion of the GSH intervention which facilitated mental health improvement.

Given the apparent effectiveness of GSH within a clinically-representative sample, it is worth considering what else may explain the current study's moderate effect sizes under conservative ITT conditions. It may be that the patients in the current study began with a milder level of symptomatology than other studies and were thus better-placed to benefit from a low-intensity intervention such as GSH. Indeed, in contrast to the study of Mead *et al*. (2005) in which the baseline combined HADS mean score was 25.26 (SD = 6.66), the corresponding baseline mean score in the present study was 19.33 (SD = 6.06). Some previous GSH studies (e.g. Lovell *et al*., 2008; Mead *et al*., 2005) have included individuals with moderate to severe anxiety or depression which may not be suited to a low intensity intervention such as GSH. However, as Mead *et al*. (2006) argue in their response to an article (Young *et al*., 2006) which debated the initial findings of Mead *et al*. (2005), it is possible that patients with initial milder symptomatology would not demonstrate any additional benefit of intervention over-and-above that which would be expected over time within a control group. With regard to this latter point, it is difficult to disentangle the argument further due to the lack of a distinct control group within the current study. Although a control period was achieved prior to intervention by participants serving as their own control, the lack of a parallel control group across the duration of the intervention makes it difficult to ascertain whether initial milder symptomatology is fundamental to GSH effectiveness, or whether

the transient nature of many of the problems targeted by low-intensity interventions is conducive to spontaneous improvement over time, irrespective of whether GSH intervention occurred.

Hypothesis 1b: Improvements in mental health and social functioning observed at post-treatment will not be maintained at 3- and 6-month follow-up.

Due to the vast majority of small effect sizes at follow-up within the clinically-representative studies reviewed within Chapter 1, it had been hypothesised that GSH effectiveness at post-treatment would not be maintained at follow-up. Contrary to this hypothesis, the improvements in anxiety, depression and work/social functioning observed across the intervention were also maintained at 3-month follow-up, again with large effect sizes within the completer analysis. At 6-month follow-up, improvements from post-treatment were no longer statistically significant for anxiety and depression outcomes, but improvement in work and social functioning remained statistically significant. Due to the mean improvement in anxiety and depressive symptoms at 6-months being considerably greater than observed in the control period and having a comparable effect size to earlier time points, it is possible that the non-significance is an artefact of the small sample size available at this stage (n = 16) rather than a true reduction in effectiveness.

Nonetheless, although comparison with the reviewed studies of Chapter 1 was more limited by the lack of ITT analyses possible at follow-up, the indication of mental health and functioning improvements being maintained at 3-month follow-up within the completer sample is consistent with some of the findings from previous studies. Of the studies reviewed within Chapter 1, a large ES (d = 0.69) was obtained for internet-GSH at 1-month follow-up of anxiety symptom improvement (Warmerdam *et al*., 2008). However, this was a non-clinical based study and was followed up at a relatively early interval. More recently, a primary care based RCT which was specific to depression found significant benefit (d = 0.42) of GSH versus treatment as usual in reducing depressive symptomatology at 8-month follow-up (Williams *et al*., 2008) suggesting that

good quality RCTs in clinical practice can demonstrate effectiveness at longer-term follow-up – at least for depression. In terms of suggested clinical effectiveness at 3-months, the discrepancy between the current findings and the clinical studies reviewed earlier could be due to a couple of reasons. For instance, the lack of a distinct control group in parallel with the intervention may have given an over-inflated sense of how effective the intervention was relative to control within the current study. Similarly, the fact that ITT analyses at follow-up were not possible for this study in contrast to the reviewed studies earlier could also explain the more conservative findings of the RCTs.

However, akin to the findings of Williams *et al*. (2008) it is possible that effectiveness at 3-months was a fair reflection of maintained improvement because GSH does continue to be effective at that stage. The possibility for this is perhaps heightened given the enduring nature of the intervention in which individuals are typically given more self-help workbooks to work through beyond the final session of the intervention. Therefore, with the premise being that the intervention is still 'active' by virtue of the person being their 'own therapist' in working through their self-help workbooks, it is possible that this ongoing learning and reflection led to continued effectiveness of GSH in the medium-term. In addition, the significant improvement in self-efficacy by intervention-end is perhaps indicative that individuals generally believed more in their own ability to enact change having progressed through and completed the intervention. As such, a sense of renewed self-efficacy may have helped maintain the mental health and functioning gains seen at 3-month follow-up.

Regarding the lack of significant improvement relative to control at 6-month follow-up, it is possible that any renewed self-efficacy and increased motivation following GSH could not be sustained in the longer-term. Alternatively, given that the mental health problems of those who access GSH are typically of a more transient nature than seen in conventional CBT, it is possible that previous psychosocial stressors re-appear or new stresses begin to manifest within the passage of time. However, these interpretations conflict with evidence of sustained improvement in work and social functioning at 6-month follow-up. In addition, the maintained moderate effect sizes at this stage suggest that had the sample size been larger, the improvement in anxiety and

depression would have remained statistically significant at 6-month follow-up. Therefore, it is perhaps more likely that a larger sample size at this point would have conveyed significantly greater improvement, particularly as GSH has been observed to be effective at longer-term follow-up in larger cohort studies (e.g. Clark *et al*., 2009). However, again this would need to be countered by the lack of ITT analysis, which could inflate the extent of maintained improvement. It is difficult to draw comparisons with the aforementioned clinically representative studies due to a range of differences specific to GSH (e.g. manual used, duration of intervention, person providing the intervention). The clinical study which used the same outcome measure (HADS) and was perhaps most similar to the current study was that of Mead *et al*. (2005). As argued previously, the baseline symptomatology of individuals in the RCT by Mead *et al*. appeared to have a severity significantly greater than that of the current study; this would clearly have implications for any difference in findings between the two studies at follow-up as well as post-treatment.

5.2 The wider impact of GSH on primary care services

Do patients have fewer contacts with services regarding their mental health and use a lower quantity of psychotropic medication in the three-month period following guided self-help intervention compared to the three-month period prior to intervention?

Analysis revealed that patients consulted GPs regarding their mental health on significantly fewer occasions in the three-month period following GSH intervention compared to the three-month period preceding their intervention. Other mental health professionals were consulted on more occasions following GSH rather than prior to GSH, but not significantly so. In addition, psychotropic medication was prescribed less often in the corresponding period following GSH compared to prior to GSH. Together, these findings indicate that GSH intervention is effective in reducing patients' consumption of primary care services. While detailed analysis of cost-effectiveness was beyond the scope of the current study, these findings are supportive of the beneficial role of minimal interventions such as guided self-help within the stepped-care model,

economically as well as clinically. The implications of these findings will be discussed later within this chapter.

5.3 Differences in GSH effectiveness between services

The current study explored the effectiveness of GSH in different services, though analysis revealed that the two main services were broadly equivalent in terms of effectiveness as evidenced by improvement in symptomatology of anxiety and depression, as well as work and social functioning, both at post-treatment and follow-up. The third service did not have a sufficient number of patients to warrant a comparison of all three services. This comparable effectiveness was found despite inherent differences between the two main services and gives greater confidence that the effectiveness is externally valid and generalisable rather than due to a spurious finding unique to the idiosyncrasies of one service. For instance: Service A was provided by one assistant psychologist at any one time, while Service B was provided by four guided self-help workers concurrently; Service A used a self-help manual specific for anxiety (Stuckey & Millar, 2003) or for depression (Williams, 2006) while Service B used a broader range of self-help materials; Service A had a significantly shorter mean GSH intervention duration than Service B. Similarly, Service A saw patients for intervention across significantly fewer sessions than in Service B. Clearly, such differences in number of appointments and duration of intervention have implications for the optimal GSH service model, as will be discussed later. The broadly similar effectiveness of GSH across these two distinct services, despite differences in service characteristics, perhaps points to the relative importance of factors specific to the intervention (e.g. self-help manuals used, CBT as the treatment modality) versus factors non-specific or common across psychological therapies (e.g. patient self-efficacy or therapeutic alliance) in delivering similar effectiveness outcomes.

5.4 Factors influencing GSH outcomes

Hypotheses 2a, 2b and 2c: Patients who have greater self-efficacy, who are of higher socio-economic status and who experience a greater therapeutic alliance with their therapist, will benefit to a greater extent from GSH in terms of improvement in mental health and social functioning.

Essentially, the above hypotheses were not supported by the evidence. Regression analyses revealed that greater improvement in anxiety symptoms was predicted by a model consisting of lower self-efficacy in the first GSH session and higher self-efficacy in the final session. Similarly, greater improvement in depressive symptoms was predicted by a model consisting of lower self-efficacy in the first session, in addition to greater therapeutic alliance as rated by the therapist in the final session. These findings will be discussed in more detail with regard to each individual predictor.

However, with regard to improvement in work and social functioning, it was surprising that none of the factors were predictive of this outcome. Although, the relationship between patient self-efficacy in the final session and improvement in work and social functioning approached significance, suggesting that there was a trend for patients' sense of coping with everyday life (in terms of work, family life, home management, social activities and private leisure activities) to improve in parallel with their increased sense of coping. Aside from exploration of the three main factors, improvement in work and social functioning was significantly correlated with parallel improvement in anxiety and, particularly, improvement in depressive symptomatology. This is evidence of the wider impact that GSH can have in not only improving mental health, but by extension improving individuals' functioning within different aspects of everyday life.

5.4.1 Self-efficacy

Patient self-efficacy was predictive of both anxiety and depressive improvement across the duration of the intervention, suggesting that patients starting GSH with lower self-

efficacy were likely to benefit from GSH to a greater extent than those starting GSH with high self-efficacy. Furthermore, patients with greater self-efficacy in the final session experienced greater anxiety improvement.

The hypothesis had asserted that those with higher self-efficacy would benefit to a greater extent from GSH than those with lower self-efficacy. This had been based on previous evidence which had indicated that higher self-efficacy facilitated better self-help outcomes (Mahalik & Kivlighan, 1988), and based on a large survey of mental health practitioners stating higher patient self-efficacy to be one of the most predictive factors of successful self-help outcomes (MacLeod *et al*., 2009). However, as was noted within Chapter 2, these studies relate almost exclusively to self-help rather than guided self-help. In contrast, an earlier guided self-help study found that higher patient self-efficacy was associated with reduced improvement in anxiety symptoms (Hutchison, 2007). It is possible that the latter finding was an indicator of a pattern specific to *guided* self-help as opposed to 'pure' or non-guided self-help, in which lower self-efficacy facilitates greater mental health improvement in guided interventions. A plausible mechanism for such a relationship could be that a patient who has low self-efficacy is more likely to have an external locus of control, thereby identifying with the therapist as being the main agent of change. Therefore, within a guided intervention such as GSH, the patient's expectancy of the therapist to enact change could enhance their engagement with the guided nature of the intervention, thereby maximising their progress across the intervention. In contrast, a patient with higher self-efficacy might be expected to have an internal locus of control, thereby identifying oneself rather than the therapist as the main agent of change. Therefore, within a guided intervention such as GSH, the patient's relatively minimised expectancy of the therapist to enact change could limit their engagement with the guided aspect of the intervention, thereby limiting their progress across the intervention.

Alternatively, it is possible that those with higher self-efficacy had milder initial symptomatology, thereby limiting the scope for greater improvement compared to those with low self-efficacy whose baseline symptomatology may have been more extensive. Indeed, a post-hoc independent t-test had indicated that when self-efficacy in the first

GSH session was categorised, albeit arbitrarily, to those with 'low' self-efficacy (scores ≤ 26) or 'high' self-efficacy (scores > 26) there were significant differences in baseline symptoms of anxiety and depression for these two groups. This raises the possibility that milder baseline symptomatology led to less of a margin for improvement in symptoms across the duration of the intervention for those with high self-efficacy. However, because the outcome variable for the regression model was the improvement in symptomatology from the first to final GSH session, the relative baseline differences are accounted for to a certain degree by virtue of the outcome variable intrinsically comprising baseline scores.

The significant role of higher self-efficacy in the final GSH session being predictive of improvement in anxiety symptoms is suggestive of the notion that as patients progress through their intervention, they become increasingly confident in their own abilities to tackle their presenting problems. There are a couple of reasons why this may have emerged as a significant predictor of anxiety improvement as opposed to depression improvement. For instance, the wider range of anxiety versus depression symptomatology at baseline may have afforded greater opportunity for this factor to influence anxiety improvement. Alternatively, it may be that the CBT skills for tackling anxiety (e.g. graded hierarchies) are more straightforward for patients to proceed with sooner than the CBT techniques for tackling depression (e.g. thought challenging) and where motivation may be more limited to facilitate improvement in depressive symptoms.

5.4.2 Therapeutic alliance

Although no evidence exists indicating the role of therapeutic alliance in influencing GSH outcomes, it had been hypothesised that greater therapeutic alliance would have facilitated greater improvement in symptoms given that the establishment of a positive therapeutic alliance is regarded as one of the *first* steps of therapy (Beck *et al*., 1979). Finding that therapeutic alliance as rated by the therapist in the final GSH session was predictive of improvement in depressive symptoms was an interesting outcome. This suggests that the development of a positive therapeutic alliance can have a significant

impact within a short-frame such as within GSH interventions. However, it may be that therapists simply view their patients more favourably if they appear to respond well to the intervention. Due to a lack of evidence on this topic, it is unclear why therapeutic alliance as rated by the *therapist* emerged as a significant predictor and why it was predictive specifically of improvement in *depressive* (as opposed to anxiety) symptoms. It is possible that the therapists' rating within the final session was the most accurate reflection of the therapeutic alliance, given the possibility that their ratings within the first session may have erred on the side of caution. Also, it is possible that the almost universal positive ratings of the therapeutic alliance by patients within the first and last sessions led to less distinction between therapeutic ratings, thus giving less scope for patients' ratings to emerge as a predictive variable. In contrast, it could be speculated that therapists' ratings within the final session offer a chance for accurate reflection on their level of engagement with their patient across the intervention and less conservatism than may have been the case in the first session. In addition, having understandably experienced therapeutic alliances significantly more often than patients, therapists may be provided with the opportunity to reflect on a greater variety of therapeutic alliances, enabling them to draw a balanced, informed judgement of the alliance relative to their wealth of previous experience.

Otherwise, it may be that therapeutic alliance as rated by the therapist was predictive only of depression improvement rather than anxiety improvement due to the benefits of a positive therapeutic alliance (e.g. empathy and a positive attachment; Bordin, 1979), directly countering symptoms more typical of depression (e.g. loneliness and social withdrawal). Also, with motivation typically being more symptomatic of depression than anxiety, it may be that improvement in depressive symptoms was more influenced by therapeutic alliance due to those patients' greater need for the motivational support of a positive other (i.e. their therapist). Additionally, it is possible that therapeutic alliance did not emerge as a significant predictor of anxiety improvement due to the key role of self-efficacy in that regard, as evidenced by the large proportion of variance explained by self-efficacy. Nonetheless, together the above findings provide the first direct evidence of the importance of therapeutic alliance in

influencing GSH outcomes despite the brevity of the intervention. This evidence is consistent with a recent meta-analysis of comparative GSH and traditional psychotherapy studies in which the resultant equivalent effectiveness was interpreted as being indicative of the contact *per se* between therapist and patient being essential rather than the *amount* of contact (Cuijpers *et al*., 2010).

Do patients' views correspond with therapists' views regarding the nature of their therapeutic alliance?

Among the 60 people who completed the GSH intervention, there was not a significant correlation between patients' and therapists' ratings of the therapeutic alliance within the first appointment. However, finding that their views were significantly correlated within the final appointment conveys that some early disparity in therapist and patient views of the therapeutic alliance did not prevent greater concordance in their views by the end of GSH intervention. It is possible that some of the early disparity could be explained by therapists being more realistic or conservative, whereas patients may have been responding in a socially desirable manner to portray the alliance favourably. This possibility had been pre-empted by reassuring patients that their responses would only be accessible to the lead researcher, not their therapist, and by asking patients to complete their therapeutic alliance rating independently of the presence of their therapist. However, it is possible that this was not always feasible in practice, and even if it was, it is possible that this was not sufficient to enable patients to respond as openly as they may have liked. As there was no significant interaction between patients' and therapists' ratings over time, it is unlikely that one half of the alliance had altered their perspective significantly more than the other half of the alliance. Rather, it is possible that the significant correspondence of therapists' and patients' ratings in the final session was due to therapists being less conservative by the final session, while simultaneously, due to a positive alliance being generated during the intervention, patients may have rated the therapeutic alliance positively as a more genuine reflection of their perception of the therapeutic alliance.

With regard to the lack of concordance between patients' and therapists' ratings in the first appointment, analyses revealed that this disparity was not significantly related to improvements in mental health or social functioning, or to distinguishing completers from non-completers. Therefore, any discordance early within the GSH intervention did not appear to adversely affect the extent to which someone subsequently benefited from GSH. It is likely that because both patients and therapists overwhelmingly rated the alliance positively (albeit differently) at this early stage, that any effect of disparity upon outcomes would have been minimised. Also apparent from analysis of the therapeutic alliance was that patients rated the therapeutic alliance significantly more highly than therapists for the duration of the intervention, suggesting that for the people who completed the intervention, they appreciated and responded well to the therapist providing their guidance. Finding that both halves of the therapeutic relationship rated the alliance significantly more highly in the final session compared to the first session is suggestive of both the patient and therapist identifying the intervention to have been suitable for patients needs for those who complete the intervention.

5.4.3 Socio-economic status

The general absence of socio-economic status within significant correlations and regression models may underline its lack of influence in determining GSH effectiveness. Therefore, despite lower SES being associated with poorer mental health outcomes (Scottish Executive, 2005), it did not seem to make a difference either way in terms of people benefiting from the intervention. This concurs with the study of Keeley *et al*. (2002) in which practitioners who were surveyed believed that SES would not be influential in determining self-help outcomes, but is in contrast to a more recent study in which practitioners generally believed that SES would be an important factor in determining effectiveness (MacLeod *et al*., 2009). However, the lack of influence of SES may have been a reflection of the sample being relatively homogeneous. Of the 60 completers, 65 per cent were categorised within the highest social class, with a further 13 per cent in the second-highest of the five social classes. Therefore, its lack of influence could be due to the relatively minimal variation in SES thereby reducing its

likelihood of predicting outcomes. However, although SES did not impact directly upon effectiveness, SES did have a role in distinguishing completers from non-completers - as will be discussed next - suggesting that this is an important factor to be considered perhaps earlier at the referral and pre-intervention stage, rather than once the intervention is underway.

5.5 Differences between GSH completers and non-completers

When comparing the scores of 60 completers versus 37 non-completers on baseline variables including: age; socio-economic status; anxiety symptomatology; depressive symptomatology; work and social functioning level; self-efficacy; and therapeutic alliance as rated by both the patient and therapist within the first GSH session, the only variable which significantly distinguished those who defaulted from those who completed the GSH intervention was socio-economic status (SES). Specifically, completers had a significantly higher SES classification than non-completers. This suggests that socio-economic status is influential in affecting individuals' engagement with GSH, which has implications for the workability of GSH across a broad demographic range, given the remit of low-intensity interventions such as GSH to increase the population's access to psychological therapies (DoH, 2005). The links between lower SES and poorer mental health outcomes are well-evidenced (Scottish Executive, 2005) and as the NS-SEC classification system captures "basic structuring principles of society such as income and housing" (Chandola & Jenkinson, 2000), the current study highlights that there is something about the GSH services analysed which limits the amount of engagement and benefit possible for less affluent areas of society. If GSH is to maximise its accessibility then it needs to be an intervention within a service which can flexibly accommodate the varying needs of different demographic strands of the population accessing such interventions.

Within the present study, the reasons are unclear as to why people of lower SES defaulted significantly more than people of higher SES and this is worthy of further investigation. However, a similar GSH cohort study has found a significant association between study dropout and employment status, alluding to a differential role of SES in

terms of GSH attendance (Farrand *et al*., 2008). In the current study, of the 37 people who defaulted, 20 did so prior to the first session, while the remaining 17 did so after attending their first session. It is possible that the same mechanism underpins this differential defaulting – for example, it could be that psychosocial stressors were simply too varied and multitudinous for people to sustain their engagement with such a low-intensity, specific intervention. Alternatively, for those non-completers who initially engaged with GSH services, their subsequent drop-out from treatment may be further indication of adults of lower SES having lower perceived confidence, knowledge and skills to enact changes necessary for resilience during sustained stress (e.g. Hibbard *et al*., 2004). As such, it is possible that adults of lower SES within the current study were sufficiently influenced by a negative self-concept regarding their ability to change, that defaulting seemed like the best option available to them. Alternatively, it may be that there was something specific to the GSH services which limited the engagement of individuals of lower SES to GSH – for instance, previous work has highlighted the influence of the readability of self-help manuals on patients' engagement with self-help (Martinez *et al*., 2008). It may be that the self-help manuals which were used in the present study were less accessible to those who defaulted due to their readability. Clearly, future studies could illuminate the mechanisms behind lower SES defaulting, perhaps with qualitative investigation which follows-up patients after they have defaulted treatment, although this could be inherently impractical.

5.6 Methodological strengths

As was documented within the preceding systematic review, this study was motivated by a lack of clinically-representative studies within the evidence-base for CBT-based GSH for anxiety and depressive disorders. The current study adds valuable evidence to the literature by virtue of sampling a relatively large number of participants within primary care and across three different settings which routinely offer GSH as a low-intensity intervention. With an evidenced tendency for GSH research to be indicative of efficacy and often lacking external validity, the current research offers generalisable, practice-based evidence to add to the limited GSH evidence base. Such an approach is

harmonious with an impetus within psychotherapy research more generally for an increased drive to obtain evidence from routine clinical practice to add to the findings from efficacy RCT studies (Cahill *et al*., 2010; Shadish *et al*., 2000). Therefore, having sampled from a clinically-representative population within established primary care settings, the indication of clinical effectiveness within the current research (and under conservative intent-to-treat conditions) offers validating evidence that guided self-help is effective in clinical practice, not just in efficacy studies. While similar effectiveness has been indicated in recent clinically-representative GSH RCT studies (e.g. Lucock *et al*., 2011; Williams *et al*., 2008), the former study lacked follow-up evaluations, while the latter was specific to depression. In contrast, the current study adds to the evidence base by investigating depression and anxiety, and by following up effectiveness outcomes beyond post-treatment. However, a caveat should be noted: the lack of a control group in parallel with the intervention may have led to an overestimation of effectiveness within the current study.

By utilising 3-month and 6-month follow-up, the present study attempted to fill a gap within the GSH evidence-base in which there tends to be an over-emphasis on post-treatment findings (e.g. NICE, 2009) rather than whether effective outcomes are maintained in the medium to longer-term. Although the high rate of attrition saw relatively small numbers of people completing outcome measures at follow-up, the emerging evidence at 3-month, and to a lesser extent 6-month, follow-up was suggestive of mental health improvement and social functioning gains being maintained in the medium-term. Given the often less-entrenched nature of mental health problems typically targeted by GSH interventions, without a follow-up evaluation it would be impossible to tell firstly, whether gains were maintained at all, and secondly to what extent people's gains at post-treatment are maintained due to the intervention or simply to the passage of time. Maintenance of gains at follow-up suggests that individuals continue to benefit having learned something specific from GSH rather than simply feeling better by having someone listen to their problems without necessarily learning anything new. In having a control period, albeit shorter than the duration of intervention, this enabled more assertion in claiming that the maintained gains were due to GSH

rather than the passage of time. However, the GSH evidence-base for effectiveness at follow-up would be bolstered further by evaluating GSH in parallel with a distinct control group.

Earlier discussion within Chapter 1 highlighted the increasing demand in GSH research for a focus upon the factors which may be predictors of treatment effect within studies due to a lack of understanding regarding who benefits from GSH (e.g. Lovell *et al*., 2008). The present study addressed this void in two ways: firstly, by exclusively focusing the research upon clearly-defined *guided* self-help interventions, not self-help in more general terms; and secondly, by investigating the impact of a variety of non-specific factors upon GSH outcomes. In examining the respective roles of patient self-efficacy, socio-economic status and therapeutic alliance within GSH, an attempt was made to explore factors beyond the specific aspects intrinsic to GSH interventions. Such an approach is consistent with observations within the evidence base that the role of non-specific, common factors is yet to be adequately addressed within self-help generally (Peck, 2010). Furthermore, the quantitative analysis of the role of therapeutic alliance in GSH appears to be a feature unique to the current study. Such a focus is worthwhile to help disentangle how important the 'guided' element of GSH actually is, and what the mechanisms behind this guidance actually are in order for it to contribute to effectiveness. Measuring therapeutic alliance from the perspective of both the patient and therapist provides additional corroboration of the alliance and increases confidence in the true extent of the therapeutic alliance.

On the theme of corroboration, the current study attempted to bolster its findings by measuring not only mental health symptomatology, but also work and social functioning, given the debilitating effect mental health problems can have in limiting the everyday aspects of people's lives. Similarly, by assessing the clinical effectiveness of GSH not only directly, but also indirectly in terms of the wider impact of GSH upon service consumption, an attempt was made to gauge the beneficial effect (or otherwise) of GSH within the stepped-care approach and clinical setting more broadly to enhance the external validity of the study. Finding that GSH was effective not only for individuals accessing those interventions, but in significantly reducing patients'

subsequent consumption of GP services, underlines the wider impact that a low-intensity intervention like GSH can have in terms of cost-effectiveness for services. In addition, finding that simultaneously having a psychotropic prescription did not differentially influence GSH effectiveness outcomes, highlights the importance of GPs having the pathway to refer individuals to an intervention like GSH – it is cost effective for GPs as an alternative to prescribing medication and by having fewer appointments with patients after their GSH attendance it increases their own service capacity. It is also likely that when GSH is effective it prevents a person's mental health problems from becoming more entrenched, thus facilitating further cost-effectiveness by reducing the likelihood that that individual will subsequently need to access higher, more specialist services within the tiered system.

5.7 Methodological limitations

The absence of a distinct control group within this study necessarily tempers the conclusions which can be drawn regarding the clinical effectiveness of GSH. Given the need for statistical power, the limited size of the population accessing GSH services within the time-frame was prohibitive of resourcing a comparable control group from that same population. In addition, the ethical ramifications of denying individuals within a control group an intervention for up to 6 months, limited the opportunity to have a control group in parallel with the intervention. However, to provide some indication of control, a design was adopted which enabled each participant to act as their own control participant, by virtue of designing a control period prior to the participant's intervention period. While the design was conceptualised for this control period to be comparable in duration to the duration of the GSH intervention (i.e. both approximately four weeks), the practicalities of conducting research within existent GSH services within clinical practice, as well as the ethical considerations described above, led to the mean duration of control and intervention periods being markedly different, particularly with respect to Services B and C, which typically operated a longer intervention duration than Service A. Despite efforts to encourage GSH services to adhere as closely as possible to the equivalent control and intervention periods this was not always possible due to a variety

of reasons, including: patients cancelling or not attending their GSH appointments; staff illness; a perceived pressure on GSH workers to see patients sooner rather than keeping them waiting; and the 'freezing' of a GSH staff vacancy once a GSH worker had left their post. Nonetheless, since participants acted as their own controls, the risk of confounding factors (other than the passage of time) was perhaps minimised. Furthermore, in demonstrating that those completers who were prescribed psychotropic medication did not benefit to any greater extent from the GSH intervention than those completers who did not have a psychotropic prescription, the possible confounding role of medication in determining effectiveness was minimised. Yet, the MHU questionnaire which participants completed within their first GSH session to indicate their medication usage merely provided a snapshot; it was not possible to ascertain the amount of time that had elapsed since an individual may have started taking medication, nor to control for a potential confounding factor in that that individual may have started taking medication after the first GSH session but while their intervention was still ongoing.

While adequate power was achieved for t-tests and correlation analyses, the lower than required sample size of 76 for regression to achieve the standard accepted power value of .80 (Cohen, 1992) necessitated a post-hoc power calculation. The regression models for anxiety improvement and depression improvement achieved power of .66 and .70 respectively. The aforementioned gap in GSH service due to a vacancy freeze meant that a GSH service was inactive for around seven months, limiting the recruitment opportunities which had been envisaged. It is unclear whether a sample size of 76 would have differentially affected the roles of therapeutic alliance, self-efficacy, and socio-economic status in influencing GSH outcomes than was otherwise indicated within the current sample.

These types of limitations are in some ways inherent in clinically-representative research, where there will be potential limitations due to issues such as imbalanced service demand and capacity, heterogeneity of GSH service provision across services, and participant attrition due to comorbid issues or unexplained issues. The high drop-out rate of 38 per cent was comparable to similar clinically-based GSH studies (43 per cent, Lucock *et al*., 2011; 46 per cent, Mead *et al*., 2005). As discussed earlier, the role of

lower socio-economic status in influencing those who dropped-out of the GSH intervention versus those who completed it highlights the potential for such non-specific factors to adversely affect engagement with GSH interventions. However, the subsequent homogeneity of higher SES within the completer sample has implications for the representativeness of the study, given that the bias towards completers being of higher social classes, limits conclusions regarding the effectiveness for individuals of lower socio-economic status.

5.8 Implications for clinical practice and policy

In the context of the wider literature, the present study adds to a limited evidence base for the effectiveness of GSH for anxiety and depression within clinically-representative populations and lends support to the inclusion of GSH within the stepped-care service model. The current study adopted a pragmatic recruitment method to maximise its external validity. Therefore, finding that GSH was equally effective across different services – despite differences in manuals, therapists, and intervention duration – suggests that the general concept of a person being guided by a therapist via a CBT-based manual is one that can be effective within routine clinical practice. For the two services which had sufficient numbers to allow comparative analysis, the differences in intervention duration and number of GSH sessions were significant. As these services were equally as effective both at post-treatment and at follow-up, this suggests that GSH may be best delivered over a shorter time-frame (i.e. 4 to 5 weeks rather than 11 weeks) and a three-session intervention (rather than 4 sessions typical of Service B). In support of this, effectiveness of GSH for anxiety and depression has recently been demonstrated in a '2 + 1' GSH model, consisting of three sessions with a total duration of 150 minutes (Lucock *et al*., 2011). Such an equivalent duration and session frequency led to effectiveness within Service A. This suggests that adopting these parameters more widely within the GSH service model would, importantly: a) ensure that patients receive and complete their GSH intervention sooner; b) allow the ongoing service throughput of

patients to occur efficiently; and c) free up more service capacity to help meet the ever-increasing demand for psychological therapies.

The preceding points have implications for services and policy in terms of the cost-effectiveness of aspects of the stepped-care model. For instance, if GSH can be delivered just as effectively across fewer appointments and within a shorter time-frame, this is likely to lead to economic efficiency, as discussed in previous literature (e.g. Bower & Gilbody, 2005). In addition, two findings within the current study add weight to the evidence outlining the wider economic impact of interventions such as GSH. Firstly, demonstrating that patients consult their GPs significantly less frequently and require less psychotropic medication following GSH compared to an equivalent time-period prior to accessing GSH, underlines the wider positive impact of minimal interventions such as GSH upon cost-effectiveness. Secondly, current evidence of significant improvement in work and social functioning following GSH – gains which were maintained at 6-month follow-up despite a small sample size – reinforces the economic benefits of increasing access to psychological therapies as proposed in key literature (e.g. Layard *et al*., 2007). Within such articles, the argument for increasing access to psychological therapies was underpinned by the message that such investment in treating anxiety and depressive disorders would pay for itself due to a subsequent reduction in related costs (fewer appointments, fewer prescriptions, and fewer welfare benefits) and increased revenues via people returning to work. The current findings are consistent with such themes, albeit the longer-term enduring benefit – both economic and clinical – of GSH remains less clear and warrants further investigation.

Clinical effectiveness was demonstrated across GSH services in the present study despite a variety of therapists with varying professional experience and qualifications; this is consistent with previous research that found no difference between professionals and paraprofessionals in effecting GSH outcomes for anxiety and depression (Boer *et al*., 2005). Given the increasing skill-mix working within psychological therapies services, consideration should be directed to the optimal staff-group to deliver such interventions, as well as the optimal staff-group to train and supervise the professionals or paraprofessionals delivering GSH. Arriving at such optimums, while ensuring the

stepped-care model remains flexible and accessible for patients, should allow precious clinical resources to be maximised to meet demand and likely lead to further efficiency with regard to cost-effectiveness.

Within the systematic review of Chapter 1, it was suggested that there remains an unrealistic perception of the amount of benefit which people can gain from GSH (Lovell *et al*., 2008). In addition, numerous authors have asserted the need for more effectiveness research of GSH within routine clinical practice (e.g. Lucock *et al*., 2008) and the systematic review highlighted the need for effectiveness outcomes to be considered in the context of study quality, recruitment setting and timing of outcome measurement. The emphasis within the current study on recruiting within a clinical population and following up GSH outcomes after post-treatment, add value in demonstrating clinical effectiveness of GSH which is maintained after intervention for patients accessing primary care services. Nonetheless, the aforementioned limitations likely have an influence on the overall quality of the current study and reinforce the need for more pragmatic RCTs of GSH within clinical practice (e.g. Lucock *et al*., 2011; Williams *et al*., 2008). Pragmatic RCTs of GSH, in maximising external validity while achieving good internal validity, are necessary to balance the existent GSH evidence base. It is hoped this would increase the likelihood that future clinical recommendations (e.g. NICE) for depression and anxiety are based on a sound, externally valid evidence base which is reflective of the heterogeneity and complexities of everyday clinical practice.

However, the evidenced effectiveness within the current study clearly does not apply to everyone who is referred to GSH. Indeed, although socio-economic status (SES) did not influence GSH improvements directly, it did have an indirect impact in that those who defaulted the GSH intervention were of significantly lower SES than those who completed GSH. While this is a trend apparent in other psychotherapy research (e.g. Lewis *et al*., 2003), this perhaps needs further attention given that low intensity interventions such as GSH are designed to maximise the public's options and access to psychological therapies. If there is a certain demographic strand (such as people with lower SES) that GSH is generally less effective for, then this has

implications for ensuring that its future delivery is equitable and accessible. As GSH therapists typically see patients at their local health centre, this perhaps lessens the likelihood that travel time or cost are prohibitive factors leading to patients of lower SES defaulting. Rather, given the perhaps greater potential for patients of lower SES to have concurrent financial, housing or health issues, it is possible that their engagement with other support services limits their ability to engage with yet another service, such as GSH. Alternatively, it may be that this format of GSH, using written manuals, is one that is not conducive to engagement with this population, given the association between lower SES and educational level, and the influence of educational level on people's engagement with self-help materials (e.g. Martinez *et al*., 2008). It is clear that there is currently a lack of understanding about what influences people of lower SES to default from GSH interventions. While future research could qualitatively attempt to follow-up those who default GSH, an onus remains on primary care services to develop equitable psychosocial interventions which are flexible to accommodate a variety of needs; emphasising the importance of engagement and maximising accessibility of stepped-care interventions such as GSH to deprived populations (e.g. STEPS; White, 2008).

5.9 Avenues for future research

In considering GSH clinical effectiveness and cost-effectiveness, it would be fruitful to discover whether future GSH studies replicate the current study in finding interventions of shorter duration consisting of three sessions to be just as effective as longer GSH interventions. Or indeed, whether both are effective but longer GSH interventions lead to larger effect sizes (e.g. Richards & Suckling, 2009) and greater clinically significant change in the longer-term.

While recent research has highlighted that expectancy of success is regarded by mental health practitioners as a factor likely to be important in facilitating self-help effectiveness (MacLeod *et al*., 2009), the importance of the individual's expectancy of what GSH actually involves is less clear. For instance, as a large proportion of GSH referrals are likely to be decided at multidisciplinary triage meetings, it is possible that the first information the individual receives about GSH will be a waitlist letter for that

GSH service. If this is the case, there is the possibility that such individuals are not able to make a fully informed choice as to their treatment pathway, which may increase the likelihood that that individual defaults from GSH. Qualitative research could examine patients' experience of this referral process to determine whether sufficient information is provided – whether by their GP initially or in a letter following triage – to enable the individual to have a realistic expectancy of what GSH involves and make a more informed decision earlier in the referral process regarding their engagement with GSH.

There still remains a need to better understand the relative influences of specific versus non-specific factors with regard specifically to GSH. Although there has been qualitative research in which practitioners have been asked about what factors influence self-help effectiveness (MacLeod *et al*., 2009), corresponding research from patients' perspective is lacking. Retrospective qualitative studies could focus on asking patients to reflect on what they recognised as being the main mechanisms of change across their experience of GSH intervention. Additionally, given that therapeutic alliance was suggested to be a mechanism of change within the current study, it would be useful to have a more refined analysis of therapeutic alliance to illuminate whether certain aspects of this (e.g. developing a secure base, empathy, rupture repair) are more important than others in influencing GSH outcomes.

While the current study endeavoured to explore the contribution of a range of factors non-specific to GSH, the potential range of factors which could have been explored was much wider. For example, a survey of CBT practitioners identified that the majority regarded patients' motivation and educational level as factors likely to facilitate self-help effectiveness (MacLeod *et al*., 2009). Ideally, future *patient*-based research will add to the patient-based evidence from the current study, in determining the relative influences of variables such as motivation and educational level versus, for example, patient self-efficacy and therapeutic alliance. As self-help materials become increasingly developed with regard to ensuring maximum readability or diversified to different media (Martinez *et al*., 2008) and greater adaptation occurs within self-help manuals of common factors such as therapeutic alliance and empathy (Richardson *et al*., 2010), the potential for interaction between such specific and non-specific factors - with regard to

both self-help and specifically guided self-help - will necessarily increase our insight into how guided self-help works for whom.

5.10 Conclusions

This study has provided evidence suggesting GSH is clinically effective in improving patients' symptoms of anxiety and depression, as well as effective in improving their work and social functioning. Evidence has also indicated that improvements – both in mental health symptomatology and everyday functioning – can be maintained at least up to 3-month follow-up. Crucially, this effectiveness has been evidenced in routine clinical practice, has been shown to apply in different GSH services despite inherent differences therein, and has had a positive effect on reducing GP consultations and prescription of medication. Thus, the current study provides validating practice-based evidence of GSH working in clinical settings. Also, effectiveness outcomes have been shown to be influenced in different ways by self-efficacy, therapeutic alliance and socio-economic status. However, there remains a need to better understand the longer-term clinical and economic effectiveness of GSH and a need to further understand for whom GSH is effective in order to inform future evidence-based practice constructively.

6. JOURNAL ARTICLE

Title

The clinical effectiveness of CBT-based guided self-help for anxiety and depression: Does it work in practice and what helps people to benefit?

Abbreviated title for running head

The effectiveness of GSH for anxiety and depression

Abstract[†]

Objectives. To determine the clinical effectiveness of guided self-help (GSH) for anxiety and depression in routine clinical practice, as well as the role of self-efficacy, therapeutic alliance and socio-economic status in influencing that effectiveness.

Design. A within-subjects design was used in which participants served as their own controls by completing measures across a control period prior to GSH intervention.

Methods. Participants accessing GSH services in routine clinical practice completed mental health (HADS) and work/social functioning (WSAS) outcome measures during a baseline period and then again at post-intervention and at three- and six-month follow-up. Self-efficacy, therapeutic alliance and socio-economic status were explored as possible predictors of effectiveness.

Results. Sixty people completed GSH, with ITT analyses indicating significant moderate improvements in anxiety, depression and functioning at post-intervention. Gains appeared to be maintained at three-month follow-up, though by six-month follow-up these were generally non-significant. Self-efficacy and therapeutic alliance emerged as significant predictors of improvement in mental health.

Conclusions. Evidence from this study suggests that GSH can be effective in clinical practice, but maintenance of improved outcomes at longer-term follow-up remains unclear. Factors non-specific to the intervention such as self-efficacy and therapeutic alliance influence the amount of improvement which patients experience within GSH.

Word Count: 200

[†] As Chapter 6 will be submitted to the *British Journal of Clinical Psychology*, it is formatted according to the author guidelines for that journal (see Appendix 13)

Introduction

There has been an impetus in the UK to improve patients' access to psychological therapies (Department of Health, 2005; Scottish Executive, 2006). This has been targeted through a stepped care model in which the intensity of intervention is matched to the severity of mental health symptoms. Reflecting this stepped care approach, National Institute for Clinical Excellence (NICE) guidelines recommend the provision of cognitive-behavioural therapy (CBT) based guided self-help (GSH) intervention for anxiety and depressive disorders (NICE, 2007, 2009). However, much of the relevant GSH evidence cited by NICE (2009) is based on self-selected rather than clinical samples and on studies which have not evaluated outcomes beyond immediate post-treatment.

Effectiveness of GSH for anxiety and depression

A comprehensive review of both self-help *and* guided self-help interventions for depression indicated greater effectiveness for guided interventions (Gellatly et al., 2007). The majority of studies reviewed by Gellatly et al. were based on self-selected, non-clinical samples with symptoms of depression and the review did not state which studies were guided versus non-guided. Other reviews or meta-analyses have not distinguished guided self-help from self-help more generally (e.g., den Boer, Wiersma, & van den Bosch, 2004). As such, our understanding of the evidence for GSH effectiveness for anxiety and depression within clinical settings remains unclear.

A recent systematic review and meta-analysis of CBT-based GSH interventions found that studies which reported GSH effectiveness were less likely to have included

follow-up mental health outcomes beyond post-treatment and were more likely to be based within self-selected or non-clinical settings rather than clinical settings (Coull & Morris, 2011). In contrast, studies which did not demonstrate GSH effectiveness tended to be based within routine clinical practice and reported data at longer-term follow-up. Furthermore, those reviewed studies reporting minimal (or no) effectiveness of GSH tended to be of a higher methodological quality. A primary objective of the current study was to determine the clinical effectiveness of guided self-help for anxiety and depression in routine clinical practice.

Factors influencing GSH outcomes

Numerous studies have highlighted the need to better understand the factors which may help explain peoples' success (or lack thereof) within low-intensity interventions such as GSH (e.g., Coull & Morris, 2011; Lovell et al., 2008; MacLeod, Martinez & Williams, 2009). It has been argued that much of the effectiveness seen within guided self-help may be due to non-specific factors (e.g. patient self-efficacy) rather than the self-help materials themselves (MacLeod et al.). The current study sought to determine whether factors such as self-efficacy, therapeutic alliance, and socio-economic status influence GSH outcomes.

No quantitative literature currently exists on the impact of therapeutic alliance on GSH outcomes for patients with depression and/or anxiety. However, establishing a positive therapeutic alliance has long been regarded as one of the first steps of therapy (Beck, Rush, Shaw, & Emery, 1979) and it seems reasonable to assume that patients' and therapists' experience of the therapeutic relationship could influence GSH

outcomes, despite only meeting for three or four sessions. Consequently, a primary objective of the current study was to examine the impact of therapeutic alliance upon GSH outcomes. Indeed, a qualitative synthesis of GSH studies suggested that the therapeutic relationship is fundamental in determining to what extent people engage with self-help materials (Khan, Bower, & Rogers, 2007).

Patient self-efficacy has been evidenced to influence self-help effectiveness outcomes (Mahalik & Kivlighan, 1988). Perhaps this is not surprising given that self-efficacy relates to a person's belief in their ability to enact desired change through their own actions; a consideration relevant to GSH where the patient is required to take ownership of their therapeutic journey from the outset. More recently, a survey of mental health practitioners highlighted patient self-efficacy as one of the variables they deemed most predictive of successful self-help outcomes (MacLeod et al., 2009). However, very little published research examines the impact of patient self-efficacy upon mental health outcomes following *guided* self-help. Hutchison (2007) evaluated GSH effectiveness and found that self-efficacy was not predictive of mental health improvement, which was contrary to expectation. As such, it remains unclear to what extent patient self-efficacy affects patient outcomes, with regard to *guided* self-help where arguably the person does not need to be self-reliant to the same extent as is necessary for pure self-help.

There appears to be ambiguity amongst therapists regarding the degree to which socio-economic status is influential in determining self-help outcomes (Keeley, Williams, & Shapiro, 2002; MacLeod et al., 2009). Patients of lower socio-economic status negatively rate their confidence, skills and knowledge in enacting change

(Hibbard, Stockard, Mahoney, & Tusler, 2004), which are likely to be important mechanisms of change within guided self-help. The current study investigated therapeutic alliance, patient self-efficacy and socio-economic status to determine whether these influenced mental health outcomes following GSH intervention.

Method

Participants

To maximise the external validity of the study, any adult (aged 18 upwards) whose referral met inclusion criteria for locally-based NHS GSH services was eligible to participate in the research. Appropriate referrals to the service comprised low mood and mild to moderate anxiety and/or depression. Those scoring over 15 on the anxiety or depression scale of the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) were typically excluded from GSH interventions and referred to a higher tier within the stepped-care system.

Design

In an attempt to achieve a control comparison while avoiding the ethical dilemma of denying patients an intervention for an extended period, each research participant acted as their own control by completing measures on two occasions separated by one month immediately prior to receiving the GSH intervention. Thus, each participant completed outcome measures approximately one month prior to beginning their GSH intervention, reflecting the typical length of wait between referral and intervention. Administration of these measures was repeated at the beginning of the first GSH session and again,

approximately one month later, at the end of the last session of the intervention. This design was adopted to provide control (i.e., T_2 - T_1) versus intervention (i.e., T_3 - T_2) periods which were comparable in order to control for any change in symptoms which may have happened spontaneously irrespective of GSH intervention.

Setting and intervention

The research was conducted in three GSH services (A, B and C) within primary care settings across Lothian. Referrals to these services were received from GPs either directly or via multi-disciplinary triage meetings. Each service provides GSH intervention across three or four sessions (each typically lasting 30-45 minutes and typically across four to eight weeks) in which the patient is guided by an assistant psychologist or guided self-help worker, who in turn is trained and regularly supervised by a practitioner psychologist in the delivery of CBT-based GSH. The GSH therapist provided guidance in the use of written CBT-based workbooks which specifically target anxiety (e.g., Stuckey & Millar, 2003; Williams, 2003) or depression (Williams, 2006).

Measures

The two main outcome measures were the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) and the Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002). Both measures are well-validated and the HADS is routinely used within many primary care services, including those involved in the current study. The WSAS is recommended for use within an 'Outcomes Toolkit' for primary care outcome research (DoH, 2008). The HADS consists of 14 self-report items: 7 anxiety and 7 depression items, each rated on a four-point Likert scale, with scores of

11 and above on each subscale being indicative of clinically significant symptomatology. The WSAS consists of five items relating to the domains of: work; home management; social leisure activities; private leisure activities; and family and relationships, with high overall scale scores indicating greater functional impairment.

The measures used to gauge therapeutic alliance, self-efficacy and socio-economic status were: the Working Alliance Inventory (WAI-s; Tracey & Kokotovic, 1989); the Generalised Self-Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995); and a self-coded version of the occupation-derived National Statistics Socio-economic Classification (NS-SEC) system (ONS, 2005). The 12-item WAI-s derives from the 36-item original version (WAI; Horvath & Greenberg, 1989) and is a self-report questionnaire, with patient and therapist versions. It comprises three subscales which encompass the level of agreement and engagement between the patient and therapist on three aspects of therapeutic alliance: the treatment goals; how to achieve the treatment goals; and the extent of acceptance, trust and confidence between the patient and therapist. Respondents are asked to rate each question on a seven-point Likert scale, with higher composite scores indicating stronger therapeutic alliance.

The 10-item Generalised Self-Efficacy Scale measures perceived ability to respond to difficult and emotional situations primarily by seeing the self as the agent of change. Participants respond to the GSES across 10 items within a range of four responses from: (1) *not at all true* to (4) *exactly true*, culminating in an overall score, with higher scores indicating greater perceived self-efficacy.

The occupation-derived National Statistics Socio-economic Classification (NS-SEC) system assigns people to social classes based upon their occupational title and

level of responsibility within their employment. It has been evidenced to have both criterion and construct validity, and is recommended for use as a standardised tool within research (Rose, Pevalin, & O'Reilly, 2005). The four-item self-coded version of NS-SEC sub-classifies a person's status into one of five categories: managerial and professional occupations; intermediate occupations; small employers and own account workers; lower supervisory and technical occupations; and, semi-routine and routine occupations.

Procedure

All patients who met the inclusion criteria for the GSH service were sent a research opt-in pack consisting of baseline questionnaires comprising the HADS, WSAS, GSES and NS-SEC. The date individuals completed the questionnaires (indicated on their returned consent form) signalled the start of the control period. Where possible, a one month control period was sought before the first session of their GSH intervention in which the GSH therapist administered the HADS, WSAS and GSES at the beginning of the session. At the end of the first session, both the research participant and therapist completed their respective versions of the Working Alliance Inventory. The same measures were repeated in the final GSH session. Finally, to examine any longer-term impact of GSH upon mental health and social functioning, participants were sent the HADS and WSAS at three- and six-month follow-up following their final GSH session.

Analysis

Power calculations were based on alpha set at $\alpha = .05$, power = .80, and anticipated medium effect sizes. A medium effect size (around $d = 0.4$) was assumed based on effect

sizes from similar studies or meta-analyses, ranging from $d = 0.19$ (Mead et al., 2005) to $d = 0.80$ (Gellatly et al., 2007). To detect differences between the intervention and control phases, paired samples t-tests were used and published power tables (Cohen, 1992) indicated a sample size of 64 was required. Multiple regression was used to explore the effect of therapeutic alliance, self-efficacy and socio-economic status on outcomes following GSH. To detect a medium effect size ($f^2 = 0.15$) for three predictor variables in multiple regression analyses, published power tables (Cohen) indicated that a sample size of 76 would be required.

Results

General and demographic information

Of 598 people invited to participate, 100 (16.7 per cent) opted-in, three of whom were excluded as they were subsequently assessed to be inappropriate for GSH. Of the 97 people remaining, 72 (74.2 per cent) were female and ages ranged from 19 to 76 ($M = 36.8$; SD = 12.5). Of these 97 participants, 37 (38 per cent) defaulted treatment: 20 dropped out prior to the first GSH session and 17 defaulted after attending the first GSH session but prior to the final session. The remaining 60 participants completed the GSH intervention; 42 (70 per cent) of whom were female and ages ranged from 20 to 76 ($M = 37.2$; SD = 12.3). Thirty-two presented primarily with anxiety-related problems, while the remainder presented with depressive-related problems. Twenty-five participants received their GSH intervention across three sessions, while 35 received their intervention across four sessions. The mean duration of the baseline control period was 26.3 days (SD = 23.9) and 59.6 days (SD = 29.8) for the intervention period. At the time

of analysis, three-month and six-month follow-up data were available for 25 and 16 participants respectively.

Effectiveness of GSH for anxiety and depression

The mean outcome scores for completers on the HADS and WSAS across the five time-points: pre-intervention (T_1); intervention-start (T_2); intervention-end (T_3); three-month follow-up (T_4); and six-month follow-up (T_5), are displayed in Table 1. Values were not imputed for missing data (e.g., where a questionnaire had mistakenly been overlooked by a participant); rather, to conservatively assess effectiveness and ensure transparency across the time-points, data were only analysed for each participant where measurements had been obtained at T_1, T_2, and T_3.

Table 1 *Anxiety, depression and functioning outcomes across time*

	HADS - Anxiety			HADS - Depression			WSAS		
	M	*SD*	n	M	*SD*	n	M	*SD*	n
Pre (T_1)	12.42	*3.05*	57*	8.16	*3.83*	57	19.64	*7.01*	44**
Start (T_2)	11.88	*3.71*	57	7.93	*3.80*	57	19.84	*7.32*	44
End (T_3)	8.19	*3.28*	57	4.74	*3.00*	57	14.77	*7.78*	44
3-month (T_4)	8.16	*4.31*	25	4.24	*2.95*	25	13.57	*8.02*	21
6-month (T_5)	9.44	*3.37*	16	5.06	*3.55*	16	14.00	*7.92*	14

* Not complete HADS data across T_1, T_2, and T_3 for n = 3, so removed from analysis.
** Not complete WSAS data across T_1, T_2, and T_3 for n = 16, so removed from analysis.

To ascertain whether these apparent improvements in mental health and social functioning across intervention and follow-up were significant compared to the control period, analyses examined whether symptom improvement by intervention-end (i.e., T_3

– T_2), 3-month (i.e., $T_4 - T_2$) and 6-month follow-up (i.e., $T_5 - T_2$) was significantly greater than any spontaneous improvement across the control period (i.e., $T_2 - T_1$). Therefore, paired t-tests were conducted to compare the degree of improvement by intervention-end, three-month and six-month follow-up to any degree of improvement across the control period (e.g., $T_3 - T_2$ versus $T_2 - T_1$). Table 2 displays the *t* and *p* values, as well as the effect size (Cohen's *d*) for each comparison. Across all three outcome measures, participants' outcomes improved significantly between the start and end of GSH intervention relative to the control period. These significant improvements relative to the control period were maintained at three-month follow-up. Despite a small sample size at six-month follow-up, improvement in work and social functioning was also maintained.

Table 2 *Improvement in anxiety, depression and functioning across the intervention and follow-up compared to the control period*

	Intervention-end versus control period	3-month follow-up versus control period	6-month follow-up versus control period
HADS - Anxiety	*n* = 57 *t* = 4.20 ***p* < .01** *d = 0.91*	*n* = 25 *t* = 3.20 ***p* < .01** *d = 1.04*	*n* = 16 *t* = 1.99 *p* = .07 *d = 0.83*
HADS - Depression	*n* = 57 *t* = 4.22 ***p* < .01** *d = 0.88*	*n* = 25 *t* = 2.62 ***p* = .02** *d = 0.74*	*n* = 16 *t* = 1.75 *p* = .10 *d = 0.74*
Work/Social functioning	*n* = 44 *t* = 3.19 ***p* < .01** *d = 0.75*	*n* = 21 *t* = 2.67 ***p* = .02** *d = 0.80*	*n* = 14 *t* = 2.50 ***p* = .03** *d = 0.92*

To conservatively assess GSH effectiveness as indicated above, intent-to-treat (ITT) analysis using the last-observation-carried-forward (LOCF) technique was used to

include those people who opted-in to the research but did not complete the GSH intervention. Therefore, for those people who defaulted GSH by end of treatment (n = 37), all pre-intervention or intervention-start scores were carried forward to post-intervention. Similarly, for those completers who had missing data (e.g., where a questionnaire had been mistakenly overlooked by the participant), LOCF was used to include these participants in the analysis. ITT analysis was based on 97 people (60 completers and 37 non-completers). Since the small sample size at follow-up would have resulted in ITT analyses at follow-up being based on estimation for the vast majority (74 per cent) of cases and therefore less meaningful, ITT analyses were conducted on post-intervention data only. Table 3 displays ITT mean and standard deviation statistics.

Table 3 *Anxiety, depression and functioning outcomes across time under ITT*

	HADS – Anxiety (N = 97)		HADS – Depression (N = 97)		WSAS (N = 91*)	
	M	*SD*	M	*SD*	M	*SD*
Pre (T_1)	12.16	*3.20*	7.79	*3.80*	18.69	*7.66*
Start (T_2)	11.73	*3.51*	7.60	*3.78*	18.70	*8.35*
End (T_3)	9.41	*3.71*	5.65	*3.54*	15.47	*8.67*

*N = 6 did not have WSAS data at pre-intervention or intervention start so could not be included via last-observation-carried-forward technique

As Table 3 conveys, under ITT, the mean scores for all three outcomes at the end of intervention (T_3) are still improved compared to intervention-start (T_2). To determine whether this improvement by post-intervention was significant compared to any

spontaneous improvement across the control period, paired t-tests were conducted as displayed in Table 4.

Table 4 *ITT analysis of improvement in anxiety, depression and functioning across the intervention compared to the control period*

	Control		Intervention				
	M	*SD*	M	*SD*	*t*	*p*	Effect size (*d*)
HADS - Anxiety	0.43	*2.04*	2.32	*3.72*	3.91	**< .01**	0.63
HADS - Depression	0.19	*2.05*	1.95	*3.49*	3.94	**< .01**	0.61
Work/Social functioning	-0.01	*4.58*	3.23	*6.80*	3.52	**< .01**	0.56

The ITT analyses illustrate that even conservatively using the last-observation-carried-forward technique to accommodate missing data, significant improvements in mental health and social functioning occurred across the duration of the intervention relative to control, as evidenced by moderate to large effect sizes. Therefore, under ITT conditions, mental health and social functioning outcomes are significantly improved at post-intervention.

Clinically significant change on HADS

As HADS subscale scores ≥ 11 typically indicate clinically significant symptomatology, the data of the 60 completers were examined to gauge what proportion of individuals experienced a clinically significant change in their symptoms. Of 38 people with clinically significant symptoms of anxiety at the start of GSH, 27 (71 per cent) no longer had clinically significant symptoms by the end of GSH intervention. Six of 15 (40 per

cent) people no longer had clinically significant symptomatology by 3-month follow-up, while 6 of 9 (67 per cent) continued to enjoy clinically significant improved anxiety symptoms at six months. Of 7 people with clinically significant symptoms of depression at the start of GSH, 6 (86 per cent) no longer had clinically significant symptoms by intervention-end.

Factors influencing mental health and social functioning outcomes

As indicated previously, improvements in mental health (HADS) and social functioning (WSAS) were represented by calculating the difference in outcome scores between intervention start and end (i.e., $T_3 - T_2$). For the completer sample only, correlation and regression analyses were conducted to explore any relationships between these 'improvement scores' in mental health and social functioning, and self-efficacy, therapeutic alliance and socio-economic status. Significant correlations were found in the following instances: HADS (anxiety) improvement by intervention-end was inversely correlated with patient self-efficacy in the first GSH session (r = -.39, p < .01), positively correlated with patient self-efficacy in the final session (r = .36, p < .01), and positively correlated with patients' perception of the therapeutic alliance in the first session (r = .27, p < .05). HADS (depression) improvement by intervention-end was inversely correlated with patient self-efficacy in the first session (r = -.34, p = .01) and positively correlated with therapists' perception of the therapeutic alliance in the final session (r = .29, p < .03). Improvement in social functioning was not correlated with self-efficacy, therapeutic alliance or socio-economic status.

Multiple linear regression was conducted to further examine the relationships indicated by correlation analysis. Thus, for a regression model with improvement in anxiety by intervention-end as the dependent variable, three independent variables (patient self-efficacy in first session; patient self-efficacy in final session; therapeutic alliance in first session) were entered into a stepwise regression analysis. The regression model was significantly predictive of outcome: $F(2, 50) = 23.68$, $p < .01$, explaining 48.6 per cent of variance in anxiety improvement. Two variables emerged as significant predictors: low patient self-efficacy as rated in the first GSH session ($\beta = -.66$, $t = 5.89$, $p < .01$) and high patient self-efficacy as rated in the final GSH session ($\beta = .63$, $t = 5.69$, $p < .01$). Collinearity statistics conveyed that these two predictors loaded on to different dimensions, indicating that there was no presence of multicollinearity in the regression model.

Regarding improvement in depressive symptoms by intervention-end, as guided by correlation analysis, patient self-efficacy in the first session and therapeutic alliance in the final session were entered into a stepwise regression analysis. The regression model was significantly predictive of outcome: $F(2, 51) = 6.40$, $p < .01$, explaining 20.1 per cent of variance in depression improvement. Two variables emerged as significant predictors: therapeutic alliance as rated by the therapist in the final session ($\beta = .30$, $t = 2.37$, $p = .02$) and low patient self-efficacy in the first GSH session ($\beta = -.29$, $t = 2.30$, $p = .03$). Again, collinearity statistics highlighted that these two predictors loaded on to different dimensions, indicating that there was no presence of multicollinearity in the regression model.

Discussion

Effectiveness of GSH for anxiety and depression

Patients' mental health and social functioning were significantly improved at post-treatment following GSH intervention, as evidenced by large effect sizes. These large effect sizes are consistent with those found in a recent, large-scale cohort study evaluating low-intensity interventions such as GSH in two IAPT sites (Clark et al., 2009). Significant improvements within the completer sample were also obtained within conservative intent-to-treat (ITT) conditions, although the ITT effect sizes were considerably more moderate as would be expected. In comparison to previous GSH studies, the post-treatment effect sizes obtained here under ITT are midway between the large post-treatment effect sizes typical of non-clinical GSH studies (e.g., Andersson et al., 2005; Furmark et al., 2009) and the small effect sizes typical of clinical GSH studies (e.g., Mead et al., 2005; Salkovskis, Rimes, Stephenson, Sacks, & Scott, 2006). However, the post-treatment effect size (ES) is comparable to the clinical-based study of Richards et al. (2003; d = 0.49) and the non-clinical based study of Warmerdam et al. (2008; d = 0.54). The current findings were also comparable with a recent pragmatic randomised controlled trial of GSH for anxiety and depression (d = 0.38; Lucock, Kirby, & Wainwright, 2011). Possible reasons for the higher effect sizes observed in the current study include: milder baseline symptomatology; different self-help manuals being differentially effective; and the lack of a distinct control group.

The apparent discrepancy between the current study and previous clinically-representative studies may be due to the current study's non-randomised design and lack

of a distinct control group. Alternatively, it may be that the patients in the current study began with a milder level of symptomatology than other studies and were thus better-placed to benefit from a low-intensity intervention such as GSH. Indeed, in contrast to the study of Mead et al. (2005) in which the baseline combined HADS mean score was 25.26 (SD = 6.66), the corresponding score in the present study was 19.33 (SD = 6.06). Some previous GSH studies (e.g., Lovell et al., 2008; Mead et al.) have included individuals with moderate to severe anxiety or depression, which are likely to be less suited to a low intensity intervention such as GSH.

As effect sizes at follow-up within previous clinically-representative studies have generally been small, it had been hypothesised that any GSH effectiveness at post-treatment would not be maintained at follow-up. Within the completer analysis, improvements in anxiety, depression and functioning appeared to be maintained at 3-month follow-up. However, it should be noted that the sample size was substantially lower at follow-up and this is one potential reason for the apparent lack of effectiveness at six-month follow-up. It is also possible that GSH was not found to be effective for anxiety and depressive symptomatology at six months because it is an intervention which does not lead to enduring benefit in the longer term, however the small sample size makes this difficult to ascertain. Nonetheless, the suggested maintenance of improved symptomatology and functioning at three months is consistent with the idea of longer-term benefit indicated by Williams et al. (2008) who reported significant benefit (d = 0.42) of GSH versus treatment as usual in reducing depressive symptomatology at 8-month follow-up within primary care. Effectiveness of GSH at follow-up may be heightened by the enduring format of GSH in which individuals are typically given more

self-help workbooks to work through beyond post-completion of the intervention. Therefore, with the premise being that the intervention is still 'active' by virtue of the person being their 'own therapist' in working through their self-help workbooks, it is possible that ongoing learning and reflection, as well as their improved self-efficacy, may lead to continued effectiveness of GSH in the medium-term. However, the fact that ITT analyses were not reported here at follow-up compared to previous GSH RCTs (e.g., Mead et al., 2005; Salkovskis et al., 2006) could explain the more conservative findings of these RCTs relative to the current study.

Factors influencing GSH outcomes

Patient self-efficacy was predictive of both anxiety and depressive improvement across the duration of the intervention, suggesting that patients starting GSH with lower self-efficacy were likely to benefit from GSH to a greater extent than those starting GSH with higher self-efficacy. It is possible that those with higher self-efficacy had milder initial symptomatology, thereby limiting the scope for greater improvement compared to those with low self-efficacy whose baseline symptomatology may have been more extensive. Alternatively, it may be an indicator of a pattern specific to *guided* self-help as opposed to 'pure' or non-guided self-help, in which lower self-efficacy facilitates greater mental health improvement in guided interventions. A plausible mechanism for such a relationship could be that a patient who has low self-efficacy is more likely to have an external locus of control, thereby identifying with the therapist as being the main agent of change. Therefore, within a guided intervention such as GSH, the patient's expectancy of the therapist to enact change could enhance their engagement

with the guided nature of the intervention, thereby maximising their progress across the intervention.

Finding that therapeutic alliance as rated by the therapist in the final GSH session was predictive of improvement in depressive symptoms was suggestive of the development of a positive therapeutic alliance being influential within a short time-frame such as within GSH interventions. It is unclear why therapeutic alliance as rated by the *therapist* emerged as a significant predictor and why it was predictive specifically of improvement in *depressive* (as opposed to anxiety) symptoms. It is possible that the almost universal positive ratings of the therapeutic alliance by patients within the first and final sessions led to less distinction between therapeutic ratings, giving less scope for patients' ratings to emerge as a predictive variable. Otherwise, it may be that therapeutic alliance as rated by the therapist was predictive only of depression improvement rather than anxiety improvement due to the benefits of a positive therapeutic alliance (e.g., empathy and a positive attachment; Bordin, 1979), directly countering symptoms more typical of depression (e.g., loneliness and social withdrawal. Additionally, it is possible that therapeutic alliance did not emerge as a significant predictor of anxiety improvement due to the key role of self-efficacy in that regard, as evidenced by the large proportion of variance explained by self-efficacy. Nonetheless, together the above findings provide useful evidence of the importance of therapeutic alliance in influencing GSH outcomes despite the brevity of the intervention. This evidence is consistent with a recent meta-analysis of comparative GSH and traditional psychotherapy studies in which the resultant equivalent effectiveness was interpreted as

being indicative of the contact *per se* between therapist and patient being essential rather than the *amount* of contact (Cuipers, Donker, van Straten, Li, & Andersson, 2010).

The lack of any relationship between socio-economic status and improvements in outcome may underline its lack of influence in determining GSH effectiveness. This interpretation is consistent with the study of Keeley et al. (2002) in which practitioners who were surveyed believed that SES was not influential in determining self-help outcomes, but conflicts with a more recent study in which practitioners generally believed that SES would be an important factor in determining effectiveness (MacLeod et al., 2009). However, the lack of influence of SES may have been a reflection of the sample being relatively homogeneous. Of the 60 completers, 65 per cent were categorised within the highest social class, with a further 13 per cent in the second-highest of the five social classes. Therefore, its lack of influence could be due to the relatively minimal variation in SES, thereby reducing its likelihood of predicting outcomes.

Strengths and limitations

With a tendency for GSH research to be suggestive of efficacy rather than effectiveness in terms of lacking external validity, the current research conducted across three different primary care services offers clinically-representative, practice-based evidence to add to the GSH evidence base. The current study also adds to the evidence base by investigating depression, anxiety and functioning outcomes, and by following up effectiveness outcomes beyond post-treatment.

However, the substantially lower numbers of participants at follow-up and consequent inability to perform ITT analyses at follow-up is a limitation. Also, the absence of a distinct control group in parallel with the intervention may have led to an overestimation of effectiveness, as may the longer duration of the intervention phase in comparison to the control phase. In addition, the homogeneity of socio-economic status across the sample has implications for the extent to which the current study is representative of the wider population accessing GSH services. The majority of completers being of higher SES necessarily limits our conclusions regarding the effectiveness of GSH for completers of lower SES and perhaps highlights an issue regarding the accessibility of GSH for individuals of lower SES. Such limitations are a feature of this type of clinically-representative research and this context needs to be acknowledged accordingly when considering the extent to which findings appear suggestive of GSH effectiveness.

In finding patient self-efficacy and therapeutic alliance to be influential in impacting upon GSH outcomes, the current study adds some insight to our understanding of who benefits from GSH (e.g., Lovell et al., 2008). Knowing that people who begin guided self-help with low self-efficacy can make significant improvements in both their mental health and self-efficacy indicates the role GSH can play in fostering the belief that a person can become the primary agent of change in dealing with their problems and life stressors. In addition, the apparent contribution of therapeutic alliance in influencing GSH outcomes, underlines the importance of considering common factors (e.g., the therapeutic relationship) as potential mechanisms of change even within brief psychotherapeutic interventions such as GSH.

Implications for clinical practice and future research

In the context of the wider literature, the present results add to the evidence base for the effectiveness of GSH for anxiety and depression within clinically-representative populations. The current results lend tentative support to the inclusion of GSH within the stepped-care service model, however the numerous methodological limitations may have led to an overestimation of GSH effectiveness. Despite differences between services in terms of manuals, therapist experience and professional qualifications, and intervention duration, finding that they were equally effective suggests that the generic format of GSH can be effective across diverse clinical settings. For the two services which had sufficient numbers to allow comparative analysis, the differences in intervention duration and number of GSH sessions were significant. As these services were equally as effective at post-treatment, this suggests that GSH may be best delivered over a shorter-time-frame (i.e., 4 to 5 weeks rather than 11 weeks) and a three-session intervention (rather than 4 sessions typical of Service B). In support of this, the effectiveness of GSH for anxiety and depression has recently been demonstrated in a '2 + 1' GSH model, consisting of three sessions with a total duration of 150 minutes (Lucock et al., 2011). An equivalent duration and session frequency seemed to lead to effectiveness within Service A, suggesting that adopting these parameters more widely within the GSH service model could, importantly: a) ensure that patients receive and complete their GSH intervention sooner; b) allow the ongoing service throughput of patients to occur efficiently; and c) free up more service capacity to help meet the ever-increasing demand for psychological therapies.

The potential range of factors non-specific to GSH which could have been explored in this study was much wider. For example, a survey of CBT practitioners identified that the majority regarded patient variables such as motivation and educational level as factors likely to facilitate self-help effectiveness (MacLeod et al., 2009). Ideally, future *patient*-based as well as practitioner-based research will add to the current patient-based study in determining the relative influences of non-specific factors such as motivation and educational level versus patient self-efficacy and therapeutic alliance. As well as an increased focus upon the impact of patient factors on GSH, self-help manuals are becoming increasingly developed to ensure maximum readability, diversified to encompass different media (Martinez, Whitfield, Dafters, & Williams, 2008), and adapted to incorporate common factors such as therapeutic alliance and empathy (Richardson, Richards, & Barkham, 2010). Therefore, the greater potential for interaction between specific and non-specific factors will necessarily require a research focus which embraces their relative contribution in what makes GSH effective for whom.

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Appendix 1 *Psychological Medicine* guidelines for authors

Editorial Policy

Psychological Medicine is a journal aimed primarily for the publication of original research in clinical psychiatry and the basic sciences related to it. These include relevant fields of biological, psychological and social sciences. Review articles, editorials and letters to the Editor discussing published papers are also published. Contributions must be in English.

Submission of manuscripts

Papers for publication from Europe and Australasia, except those on genetic topics, should be addressed to the UK Editor, Professor Robin Murray, C/O Lynet Smith, Psychological Medicine Editorial Office, Cambridge University Press, UPH Building, Shaftesbury Road, Cambridge, CB2 8BS, Email: lsmith@cambridge.org.

Papers from the Americas, Asia, Africa and the Middle East, and all papers dealing with genetic topics, irrespective of country, should be sent to the US Editor, Professor Kenneth S. Kendler, MCV, PO Box 980126, Richmond, VA, 23298-0126, USA (Street address: Virginia Biotechnology Center One, Room 1-123, 800E Leigh Street, Richmond, VA, 23219, USA), Email: bherrmann@vcu.edu

Submissions by email attachments are preferred. Alternatively contributors who wish may send one hard copy of the text, tables and figures, plus an identical copy on computer disk, giving details of format used (e.g. MS Word etc.). All files should be editable, eg Microsoft Word format. Please do not attach pdf files. Authors should also accompany their submission with a list of 5 or more suggested suitable referees to aid the peer review process.

A covering letter signed by all authors should confirm agreement to submission. The letter should also give full mailing, fax and email contact details of the author who will handle correspondence. Submission of a paper will be held to imply that it contains original work that has not been previously published and that it is not being submitted for publication elsewhere. This should be confirmed in the letter of submission. When an article has been accepted for publication, the authors should email their final version or send a copy on computer disk (indicating format used, e.g. Mac/PC, MS Word/Word Perfect, etc.) together with one hard copy of the typescript and good quality copies of all tables, figures, etc. However, the publisher reserves the right to typeset the material by conventional means if an author's disk proves unsatisfactory.

The following information must be given on the first page (title sheet): (1) title and short title for running head (not more than 60 characters): (2) authors' names, (3) department in which the work was done, (4) word count of text excluding abstract, tables/figures and reference list. Generally papers should not have text more than 4500 words in length (excluding these sections) and should not have more than a combined total of 5 tables and/or figures. Papers shorter than these limits are encouraged. For papers of unusual importance the editors may waive these requirements. A structured abstract of no more than 250 words should be given at the beginning of the article using the headings: Background; Methods; Results; Conclusions. The name of an author to whom correspondence should be sent must be indicated and a full postal address given in the footnote. Any acknowledgements should be placed at the end of the text (before the References section).

Declaration of Interest: A statement must be provided in the acknowledgements listing all financial support received for the work and, for all authors, any financial involvement (including employment, fees, share ownership) or affiliation with any organisation whose financial interests may be affected by material in the manuscript, or which might potentially bias it. This applies to all papers including editorials and letters to the editor.

Contributors should also note the following:
1. S.I. units should be used throughout in text, figures and tables.
2. Authors should spell out in full any abbreviations used in their manuscripts.
3. Foreign quotations and phrases should be followed by a translation.
4. If necessary, guidelines for statistical presentation may be found in: **Altman, D. G., Gore, S. M., Gardner, M. J. & Pocock, S. J.** (1983). Statistical guidelines for contributors to medical journals. *British Medical Journal* **286**, 1489-1493.

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(1) The Harvard (author-date) system should be used in the text and a complete list of References cited given at the end of the article. In a text citation of a work by more than two authors cite the first author's name followed by *et al*. (but the names of all of the authors should be given in the References section). Where several references are cited together they should be listed in rising date order.

(2) The References section should be typed in alphabetical order on a separate sheet. Examples follow:
Brown, G. W. (1974). Meaning, measurement and stress of life events. In *Stressful Life Events:Their Nature and Effects* (ed. B. S. Dohrenwend and B. P. Dohrenwend), pp. 217-244. John Wiley: New York.
Brown, J. (1970). *Psychiatric Research*. Smith: Glasgow.
Brown, J., Williams, E. & Wright, H. (1970). Treatment of heroin addiction. *PsychologicalMedicine* **1**, 134-136.
Note: authors' names should be in **bold** font; journal titles should always be given in full.

(3) References to material published online should follow a similar style, with the URL included at the end of the reference, with the accession date, if known. Authors are requested to print out and keep a copy of any online-only information, in case the URL changes or is no longer maintained. Examples follow:
Acute Health Care, Rehabilitation and Disability Prevention Research - National Center for Injury Prevention and Control. (http://www.cdc.gov/ncipc/profiles/acutecare/default.htm). Accessed 7 June 2004.
British Psychological Society Research Digest, Issue 12. (http://lists.bps.org.uk/read/messages?id=1423). Accessed 17 February 2004.

Figures and tables

Only essential figures and tables should be included. Further tables, figures, photographs and appendices, may be included with the online version on the journal website. *Photographs* Unmounted photographs on glossy paper should be provided. Magnification scales, if necessary, should be lettered on these. Where possible, prints should be trimmed to column width (i.e. 70 mm). *Diagrams* These should not be included in the text and should be submitted in a form suitable for direct reproduction. The printed version will normally be reduced to 70 mm wide, so care should be taken to ensure that lettering and symbols will remain clearly legible. All photographs, graphs, and diagrams should be referred to as figures and should be numbered consecutively in Arabic numerals. Ensure that the figure number is marked on the back of the photograph or artwork together with the name of the author and paper title. Captions for figures should be typed double-spaced on separate sheets. *Tables* Tables should be numbered consecutively in the text in Arabic numerals and each typed on a separate sheet after the References section. Titles should be typed above the table.

Appendix 2 Excluded studies and reasons for exclusion

Study	*Reason(s) for exclusion*
Andersson *et al.* (2006)	- 'Minimal contact' intervention also involved group exposure therapy.
Beck *et al*. (1994)	- Not a CBT-based GSH intervention (cognitive therapy vs. relaxation training).
Berger *et al*. (2009)	- No follow-up period.
Bilich *et al*. (2008)	- 'Minimal contact' condition did not involve guidance – i.e. purely assessment & monitoring. - 'Assisted self-help' condition involved 4 hours of assistance/guidance (i.e. > 3 hours).
Carlbring *et al*. (2001)	- 'Minimal contact' condition less than minimum criterion of 30 minutes of guidance.
Carlbring *et al*. (2003)	- 'Minimal contact' condition did not involve guidance.
Christensen *et al*. (2004)	- No assessment of a diagnosis or cut-off score to establish caseness.
Christensen *et al*. (2006)	- Self-help conditions did not involve guidance.
Clarke *et al*. (2005)	- 'Minimal contact' condition did not involve guidance.
den Boer *et al*. (2007)	- Intervention based on IPT as well as CBT. - Therapist contact greater than 3 hours (approximately 10 hours).
Febbraro (2005)	- No assessment of a diagnosis or cut-off score to establish caseness.
Gould & Clum (1995)	- 'Minimal contact' condition did not involve guidance.
Hegerl *et al*. (2010)	- No follow-up data reported.
Jamison & Scogin (1995)	- 'Minimal contact' condition did not involve guidance.
Kupshik & Fisher (1999)	- Non-randomised design.
Lovell *et al*. (2003)	- Non-randomised design.
Lovell *et al*. (2006)	- Therapist input greater than criterion of maximum 3 hours (> 5 hours).
Lucock *et al*. (2008)	- Non-randomised design.
Proudfoot *et al.* (2004)	- 'Minimal contact' condition did not involve guidance.
Reeves (2010)	- Non-randomised design. - Therapist input greater than criterion of maximum 3 hours.
Reeves & Stace (2005)	- Non-randomised design.
Seekles *et al*. (2009)	- Multi-component intervention, not solely guided self-help.
Smit *et al*. (2006)	- Not solely a CBT-based GSH intervention. - Therapist input greater than criterion of maximum 3 hours.
Sorby *et al.* (1991)	- 'Minimal contact' condition less than criterion of minimum 30 minutes of guidance.
Titov *et al*. (2008a)	- No follow-up period.
Titov *et al*. (2008b)	- No follow-up period.
Titov *et al*. (2008c)	- No follow-up period.
van Straten *et al*. (2008)	- No assessment of a diagnosis or cut-off score to establish caseness. - Not a CBT-based GSH intervention (problem-solving therapy).

Appendix 3 Participant information sheet

Research Participant Information Sheet

Study title: What helps people to benefit from guided self-help?

Invitation

You have recently been referred to the …….guided self-help service within NHS Lothian. There is a research study taking place in the guided self-help service, and you are invited to take part in it if you wish. Before you decide, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Please take enough time to decide whether or not you wish to take part. Thank you for reading this information sheet.

Why are we doing this study?

Many studies have suggested that self-help is a useful treatment for a range of mental health problems. However, few studies have looked at what factors may help people to benefit from guided self-help. Our study will see if any of the following factors can help people to benefit from guided self-help treatment:

- Patient's confidence in their own ability to solve problems and make changes
- Degree of rapport between the patient and the guided self-help therapist
- Patient's level of employment

Why have I been chosen?

We are asking everyone who is referred to the guided self-help service to take part in this study. We are hoping to include 76 people in this study.

Do I have to take part?

No. You are under no obligation to take part. If you decide not to take part in the study or to withdraw, this will have no effect upon your treatment within the guided self-help service or any future treatment. However, if you do decide to take part, you are still free to withdraw from the study at any time without having to give a reason. We would suggest that you wait at least 24 hours to decide on whether to take part in this study.

What will happen to me if I take part in this research?

If you do decide to take part, please **keep this information sheet** and **please sign and return the enclosed consent form** within the stamped, addressed envelope within **two** weeks of receiving this information. **Please also complete and return the four short questionnaires** in the same envelope. These questionnaires include the **Hospital Anxiety and Depression Scale**, the **Work and Social Adjustment Scale** and the **General Self-Efficacy Scale,** and **several brief questions about your occupation**. They should take **no longer than 10 minutes** in total to complete. You will be asked to complete these questionnaires again during your first and last appointments with your guided self-help therapist, and possibly midway through your contact

with the guided self-help service. Copies of these questionnaires will also be sent in the post to you three months, six months and twelve months after your final appointment. You will receive a stamped, addressed envelope on each occasion, in order to send the questionnaires back.

Also, in your first and final guided self-help appointment, you will be asked to complete the **Working Alliance Inventory** which should take no more than 5 minutes to complete. In the last appointment with your guided self-help therapist, the Client Satisfaction Questionnaire is routinely used to get feedback from you about your guided self-help treatment. Again, this should take no longer than 5 minutes to complete.

Lastly, to get an idea of how the guided self-help service may impact upon your need to visit your GP regarding your mental health and your need for medication, you will be asked a few brief questions about this in your first appointment with your guided self-help therapist and three months after you have completed your guided self-help treatment. This information will also be examined in your GP records. **Across the whole study, the total time of your involvement is likely to be around 60 minutes.**

What are the possible disadvantages and risks of taking part?
Apart from the time it takes to fill in the questionnaires, there are no other disadvantages or risks in taking part.

What are the possible benefits of taking part?
Taking part in this research will not make any difference to the treatment you receive, or how much benefit you obtain from it. However, the information we get will hopefully be useful in helping us to learn what helps people to benefit from guided self-help treatment and to ensure we provide a service which is as effective as it can be.

Will my information be kept confidential?
Yes. Any information that is collected will be stored securely, and will remain confidential. Only the lead researcher involved in the running of this study will be allowed access to such information. If the study is presented or published, all identifying information will be removed so that no research participants can be identified.

What will happen to the results of the research study?
Once this study ends in August 2011, it is hoped that our findings will be published in an academic journal. If you indicate on the consent form that you would like a copy of the main findings from the study, I will be happy to send this to you.

Who has reviewed the study?
This research has been ethically reviewed and approved by the University of Edinburgh Ethics Committee and assessed by the South East Scotland Research Ethics Service as not requiring further ethical review.

Contact for further information
If you wish to discuss any aspect of this research, please contact Greig Coull, Trainee Clinical Psychologist at the Psychology Department, St John's Hospital, on 01506 523615.
Many thanks for taking the time to read this information sheet.

Greig Coull (Lead Researcher)

Appendix 4 Participant consent form

Research Participant Consent Form

Study title: *What helps people to benefit from guided self-help?*

Lead Researcher: *Greig Coull, Trainee Clinical Psychologist*

(Please circle)

- I confirm I have read and understood the attached 'Research Participant Information Sheet'.	Yes	No
- I understand that my participation is voluntary and that I can withdraw from this study at any time, without having to give a reason, without my care or legal rights being affected.	Yes	No
- I understand that any data regarding my participation within this study will be stored safely, securely, confidentially and will only be accessible to the Lead Researcher.	Yes	No
- I consent to take part in this study.	Yes	No
- I would like to receive a copy of the key findings from this study.	Yes	No

Signed _____ (patient signature) Print Name _____ (patient name) Date _____

Signed _____ (researcher signature) Print Name _____ (researcher name) Date _____

Appendix 5 Hospital Anxiety and Depression Scale

NAME_____ **DATE**_____

This questionnaire is designed to help us know more about how **you** feel. Please read each item and place a tick in the box opposite the reply that comes closest to how you have been feeling **in the past week.** Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or 'wound up':
- Most of the time
- A lot of the time
- Time to time, Occasionally
- Not at all

I feel as if I am slowed down:
- Nearly all the time
- Very often
- Sometimes
- Not at all

I still enjoy the things I used to enjoy:
- Definitely as much
- Not quite so much
- A little but it doesn't worry me
- Not at all

I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all
- Occasionally
- Quite often
- Very often

I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly
- Yes, but not too badly
- A little, but it doesn't worry me
- Not at all

I have lost interest in my appearance:
- Definitely
- I don't take as much care as I should
- I may not take quite as much care
- I take just as much care as ever

I can laugh and see the funny side of things:
- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

I feel restless as if I have to be on the move:
- Very much indeed
- Quite a lot
- Not very much
- Not at all

Worrying thoughts go through my mind:
- A great deal of the time
- A lot of the time
- From time to time, but not too often
- Only occasionally

I look forward with enjoyment to things:
- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- hardly at all

I feel cheerful:
- Not at all
- Not often
- Sometimes
- Most of the time

I get sudden feelings of panic:
- Very often indeed
- Quite often
- Not very often
- Not at all

I can sit at ease and feel relaxed:
- Definitely
- Usually
- Not often
- Not at all

I can enjoy a good book or radio or TV programme:
- Often
- Sometimes
- Not often
- Very seldom

A_____ D_____

Appendix 6 Work and Social Adjustment Scale

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems look at each section and determine on the scale provided how much your problem impairs your ability to carry out the activity.

1. **WORK -** If you are retired or choose not to have a job for reasons unrelated to your problem, please tick N/A (not applicable)

0	1	2	3	4	5	6	7	8	N/A
Not at all		Slightly		Definitely		Markedly		Very severely	I cannot work

2. **HOME MANAGEMENT** – Cleaning, tidying, shopping, cooking, looking after home/children, paying bills etc

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly		Very severely

3. **SOCIAL LEISURE ACTIVITIES -** With other people, e.g. parties, pubs, outings, entertaining etc.

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly		Very severely

4. **PRIVATE LEISURE ACTIVITIES –** Done alone, e.g. reading, gardening, sewing, hobbies, walking etc.

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly		Very severely

5. **FAMILY AND RELATIONSHIPS –** Form and maintain close relationships with others including the people that I live with

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly		Very severely

Appendix 7 Generalised Self-efficacy Scale

For each of the following statements, please indicate the extent to which you think it is true of you. Please circle one number for every statement. As these statements are all beliefs you might or might not hold about yourself, there are no right or wrong answers.

1 = Not at all true 2 = Hardly true 3 = Moderately true 4 = Exactly true

1	I can always manage to solve difficult problems if I try hard enough.	1 2 3 4
2	If someone opposes me, I can find the means and ways to get what I want.	1 2 3 4
3	It is easy for me to stick to my aims and accomplish my goals.	1 2 3 4
4	I am confident that I could deal efficiently with unexpected events.	1 2 3 4
5	Thanks to my resourcefulness, I know how to handle unforeseen situations.	1 2 3 4
6	I can solve most problems if I invest the necessary effort.	1 2 3 4
7	I can remain calm when facing difficulties because I can rely on my coping abilities.	1 2 3 4
8	When I am confronted with a problem, I can usually find several solutions.	1 2 3 4
9	If I am in trouble, I can usually think of a solution.	1 2 3 4
10	I can usually handle whatever comes my way.	1 2 3 4

Appendix 8 Socio-economic status questionnaire

As explained in the research information sheet that you received with this questionnaire*, we are interested in finding out what effect people's level of employment may have in helping people to benefit from guided self-help. There are 4 brief questions below. Please tick just **one** box per question.

Question 1: Employee or self-employed

'Do (did) you work as an employee or are (were) you self-employed?'

Employee □ Self-employed with employees □
Self-employed/freelance without employees (go to Question 4) □

Question 2: Number of employees

For *employees*: 'How many people work (worked) for your employer at the place where you work (worked)?'……

For *self-employed*: 'How many people do (did) you employ?'
(Go to question 4 when you have completed this question.) 1 to 24 □ 25 or more □

Question 3: Supervisory status

'Do (did) you supervise any other employees?' (A supervisor or foreman is responsible for overseeing the work of other employees on a day-to-day basis.) Yes □ No □

Question 4: Occupation

Please tick **one** box to show which best describes the sort of work that you do.
If you are not working now, please tick **one** box to show what you did in your last job.

- Modern professional occupations such as: teacher; nurse; physiotherapist; social worker; welfare officer; artist; musician; police officer (sergeant or above); software designer… □

- Clerical and intermediate occupations such as: secretary; personal assistant; clerical worker; office clerk; call centre agent; nursing auxiliary; nursery nurse… □

- Senior managers or administrators (usually responsible for planning, organising and co–ordinating work, and for finance) such as: finance manager; chief executive… □

- Technical and craft occupations such as: motor mechanic; fitter; inspector; plumber; printer; tool-maker; electrician; gardener; train driver… □

- Semi–routine manual and service occupations such as: postal worker; machine operative; security guard; caretaker; farm worker; catering assistant; receptionist; sales assistant… □

- Routine manual and service occupations such as: HGV driver; van driver; cleaner; porter; packer; sewing machinist; messenger; labourer; waiter/waitress; bar staff… □

- Middle or junior managers such as: office manager; retail manager; bank manager; publican; restaurant manager; warehouse manager… □

- Traditional professional occupations such as: accountant; solicitor; medical practitioner; scientist; civil/mechanical engineer… □

*derived from the Office for National Statistics

Appendix 9 Mental Health Utilisation questionnaire

Dear Research Participant,

Thank you for agreeing to participate in this research study. As I explained in the information sheet you received at the start of the research study, I would like to ask you a few brief questions about your contact with your GP regarding your mental health and your use of medication to treat anxiety or depression within the past three months. I appreciate that this may be difficult to remember, and if so, please can you give your best guess. Please find the questions outlined below and once you are finished if you could please hand it back to your guided self-help therapist.

Best wishes,

Greig Coull
Trainee Clinical Psychologist and Lead Researcher

---

1. Within the past 3 months, approximately how many times have you visited your GP mainly because of mental health problems (e.g., anxiety and/or depression)?.....

2. Within the past 3 months, have you consulted any other mental health professionals (e.g., community psychiatric nurse, psychiatrist, etc) regarding your mental health problems (and if so, how many times?)?.....

3. Within the past 3 months, have you had a prescription for any anti-depressant medication (e.g., citalopram, fluoxetine, seroxat, sertraline, venlafaxine, etc...) and if so, what is the medication and daily dosage?.....

4. If you are currently taking anti-depressant medication, what is the type and daily dosage?……

Appendix 10 South East Scotland Research Ethics Service documentation

South East Scotland Research Ethics Service

Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
Tel: 0131 536 9067
Fax: 0131 536 9346

NHS Lothian

Name: Greig Coull
Address: Department of Psychology
St. John's Hospital
Howden Road West, Livingston
EH54 6PP

Date: 28/04/2009
Your Ref:
Our Ref: NR/0904AB10
Enquiries to: Alex Bailey
Extension:
Direct Line: 0131 536 9050
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Greig,

Full title of project: Evaluating the effectiveness of a guided self-help service

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (IRAS form: 09/S1102/16), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees in the UK. The advice is based on the following:

- *The project is an opinion survey seeking the views of NHS staff and patients on service delivery.*
- *The project is an opinion survey seeking the views of NHS staff and patients on a service development*

If this project is being conducted within NHS Lothian you should inform the relevant local Quality Improvement Team(s).

Please note that this advice is issued on behalf of the Research Ethics Service and does not constitute a favourable opinion or an endorsement from a Research Ethics Committee. It may be provided to journal editors, conference organisers or others who require evidence of consideration of the need for ethical review prior to publication or presentation of your results. If you wish you may still decide to apply to a REC, but note that a retrospective ethical opinion cannot be given.

You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service

Enclosure: NRES leaflet - "Defining Research"

1

Appendix 11 NHS Lothian Research and Development ethical approval

University Hospitals Division
Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

NHS Lothian

DEN/JB/approval/2f,8

02 July 2009

RESEARCH & DEVELOPMENT
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@luht.scot.nhs.uk

Director:
Professor David E Newby

Dr Greig J Coull
Department of Psychology
St. John's Hospital
Howden Road West
Livingston
EH54 6PP

Dear Dr Coull

MREC No:	**N/A**
CRF No:	**N/A**
LREC No:	**09/S1102/16**
R&D ID No:	**2009/SJ/PSY/03**
Title of Research	*Evaluating the role of therapeutic alliance, patient self-efficacy and socio-economic status upon guided self-help outcomes.*
Protocol No/Acronym:	**Version1.0 dated 06 April 2009**

The above project has undergone an assessment of risk to NHS Lothian and review of resource and financial implications. I am satisfied that all the necessary arrangements have been set in place and that all Departments contributing to the project have been informed.

I note that this is a single centre study and that co-sponsorship between the University of Edinburgh and NHS Lothian has been discussed and appropriate responsibilities agreed.

Following a REC final favourable approval, copies of all final study documentation (with revised version numbers) should be sent, with the REC letter of favourable opinion, to the R&D office.

On behalf of the Chief Executive and Medical Director, I am happy to grant management approval from NHS Lothian to allow the project to commence, subject to the approval of the appropriate Research Ethics Committee(s) having also been obtained. Please note that this letter also provides Site Specific approval for **NHS Lothian.** You should note that any substantial amendments must be notified to the relevant Research Ethics Committee and to R&D Management with approval being granted from both before the amendments are made.

This letter of approval is your assurance that NHS Lothian is satisfied with this project. For approved research, NHS Lothian will provide cover for negligence for NHS and Honorary clinical staff for research associated with their clinical duties. It is not empowered to provide non-negligent indemnity cover for patients.

As Chief Investigator or local Principal Investigator, you should be fully committed to your responsibilities within the Research Governance Framework for Health and Community Care, an extract of which is attached to this letter.

Yours sincerely

Professor David E Newby
R&D Director

enc	**Research Governance Certificate**	**☑ (to be signed and returned)**
	Tissue Policy (if applicable)	**☐**
	MTA (if applicable)	**☐ (to be signed and returned)**
cc	***Administrators, Research Ethics Committee***	

"Improving health through excellence and innovation in clinical research"

Appendix 12 Caldicott approval

Lothian NHS Board

Public Health & Health Policy
Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
Telephone 0131 536 9000
Fax 0131 536 9009
www.nhslothian.scot.nhs.uk

NHS Lothian

Dr Greig Coull
Trainee Clinical Psychologist
Department of Psychology
St John's Hospital
LIVINGSTON
EH54 6PP

Date 2nd June 2009
Your Ref
Our Ref JS/EM/0953

Enquiries to Jim Sherval
Extension 89374
Direct Line 0131 536 9374
Direct Fax 0131 536 9164
Email Jim.Sherval@nhslothian.scot.nhs.uk

Dear Dr Coull

Caldicott Approval: Evaluating the effectiveness of a guided self-help service

Thank you for the information supplied.

Request received from	Dr Greig Coull, Trainee Clinical Psychologist and Chief Investigator
Summary of proposal	CHI data will be used solely to identify patients registered at GP practices in order to link those people to their research data held within a secure password-protected database within the chief investigator's office (within the Department of Psychology, St John's Hospital). The chief investigator's (CI) database will link a patient's CHI number with an independent and unique code identifier, such that when the CI is off-site at a GP practice, he can initially search GP records using the patient's CHI number. Once a patient's GP record is then displayed, all information then recorded (i.e. the research participant's frequency of GP consultations regarding their mental health and prescription of antidepressant medication within the previous 3-month period) will be recorded solely in connection with the patient's unique code identifier.
Patient identifiable information requested	CHI number
Approved	Yes ✗
Reason for decision	Part of research study where participants will give consent to access to their records.
Advice	This approval does not give automatic access to GP records of living patients. Access to GP records is controlled by each practice.

Yours sincerely

Dr Alison McCallum
Director of Public Health & Health Policy

cc Dr Neil Millar, Clinical Psychologist, St John's Hospital

✗ If linkage & encryption undertaken by HIU so that participants with best practice guidance

Appendix 12 (continued) Caldicott approval

Coull, Greig

From: Coull, Greig
Sent: 30 July 2009 19:14
To: 'Purser, Harry'
Cc: Millar, Neil
Subject: RE: Caldicott approval

Hello Harry,

Many thanks for your speedy replies.

Yes, I believe our understandings match up! - I'm simply intending to use the CHI information (present on the referral letters which we receive here in our department) in order to access the relevant information from the patient primary care record. Subsequently, yes, that clinical information would be transferred to a fully anonymised local research database which does not refer to any CHI numbers/patient-identifiable information.

Thanks again and best wishes,

Greig

From: Purser, Harry [mailto:Harry.Purser@nhslothian.scot.nhs.uk]
Sent: 29 July 2009 15:53
To: Coull, Greig
Subject: RE: Caldicott approval

Hello again Greig

Having read your proposal and Caldicott form I don't think there is any special procedure we need to follow here. Can you tell me – where are you obtaining the patient CHI numbers from ? Are these included in your standard referral letters/forms ? If they are – and you are simply using them to access the relevant primary care record on GPASS (assuming the practices involved give their approval for this type of research access) – I don't see a need for any special procedures.

I think Dr Alison McCallum may have thought you were trying to link records using the CHI – but as I understand it – you are simply using it as a means of accessing individual primary care records and then transferring the appropriate clinical information to a fully anonymised database that you will maintain locally.

I therefore can't see any role for the Health Intelligence Unit in this proposal. So I think you can proceed with your proposal as stated. If I have misunderstood what is involved – please do get back to me – but I think I'm clear that there is no record linkage involved and no patient-identifiable information on your local research database.

Best Wishes

Harry Purser
Head of Health Intelligence

Appendix 13 *British Journal of Clinical Psychology* guidelines for authors

The British Journal of Clinical Psychology publishes original contributions to scientific knowledge in clinical psychology. This includes descriptive comparisons, as well as studies of the assessment, aetiology and treatment of people with a wide range of psychological problems in all age groups and settings. The level of analysis of studies ranges from biological influences on individual behaviour through to studies of psychological interventions and treatments on individuals, dyads, families and groups, to investigations of the relationships between explicitly social and psychological levels of analysis.

The following types of paper are invited:

• Papers reporting original empirical investigations

• Theoretical papers, provided that these are sufficiently related to the empirical data

• Review articles which need not be exhaustive but which should give an interpretation of the state of the research in a given field and, where appropriate, identify its clinical implications

• Brief reports and comments

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers should normally be no more than 5000 words (excluding abstract, reference list, tables and figures), although the Editor retains discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Submission and reviewing

All manuscripts must be submitted via http://www.editorialmanager.com/bjcp/. The Journal operates a policy of anonymous peer review.

4. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded from here.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary

background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

• For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright. For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.